Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Pertuzumab (Perjeta®)

Roche Pharma AG

Modul 4A

Anhang 4-G

Adjuvante Behandlung von erwachsenen Patienten mit HER2-positivem frühem Brustkrebs mit hohem Rezidivrisiko (nodal-positiv oder Hormonrezeptor-negativ)

Ergänzende Analysen

Stand: 27.09.2022

Anhang 4-G: Ergänzende Analysen der Studie APHINITY

Endpunkte der Studie APHINITY 4
Wirksamkeit (Datenschnitt: 19.12.2016) 4
Time-to-Event (TTE) Analysen 4
Stratifiziert 4
Subgruppen 12
KM Plots 22
Responder Analysen 33
Stratifiziert 33
Landmark Analysen 36
Stratifiziert 36
Wirksamkeit (Datenschnitt: 19.06.2019) 40
Time-to-Event (TTE) Analysen 40
Stratifiziert 40
Subgruppen 44
KM Plots 51
Responder Analysen 55
Stratifiziert 55
Landmark Analysen 57
Stratifiziert 57
Wirksamkeit (Datenschnitt: 10.01.2022) 61
Time-to-Event (TTE) Analysen 61
Stratifiziert 61
Subgruppen 69
KM Plots 79
Responder Analysen 87
Stratifiziert 87
Landmark Analysen 89
Stratifiziert 89
Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016) 96
Responder Analysen 96
Stratifiziert 96
MID = 15 96
MID = 10 120
Unstratifiziert + Subgruppen 144

MID = 15 144
Mixed Model for Repeated Measure (MMRM) Analysen 322
Stratifiziert 322
Rücklaufquoten 346
Unstratifiziert + Subgruppen 346
Mean Plots 761
Verträglichkeit (Datenschnitt: 19.12.2016) 785
Responder Analysen 785
Generelle Verträglichkeit 785
Unstratifiziert + Subgruppen 785
Verträglichkeit (Datenschnitt: 19.06.2019) 796
Responder Analysen 796
Generelle Verträglichkeit 796
Unstratifiziert + Subgruppen 796
Verträglichkeit (Datenschnitt: 10.01.2022) 813
Responder Analysen 813
Generelle Verträglichkeit 813
Unstratifiziert + Subgruppen 813
Generelle Verträglichkeit nach SOC/PT 825
Unstratifiziert + Subgruppen 825
Spezifische Verträglichkeit 7595
Unstratifiziert + Subgruppen 7595
Outcome 7622
Post Treatment AE 7625
Sonstige Analysen (Datenschnitt: 19.12.2016) 7639
Anzahl Zentren, Länder, Regionen 7639
Todesfälle 7641
Demographische und allgemeine Charakteristika 7643
DFS Ereignisse mit und ohne Tod 7647
Verteilung der Patienten pro Arm 7649
Follow-up time (DFS) 7652
Auflistung der Rezidive 7654
Stratifizierungsfaktoren 7676
Sonstige Analysen (Datenschnitt: 19.06.2019) 7678
Todesfälle 7678
Unerwünschte Ereignisse die zum Tode führen 7680

Unerwünschtes Ereignis: Diarrhö 7683
Verteilung der Patienten pro Arm 7686
Follow-up time (UE, SUE, OS) 7689
Sonstige Analysen (Datenschnitt: 10.01.2022) 7693
Todesfälle 7693
DFS Ereignisse mit und ohne Tod 7695
Interventionen (Post Treatment) für Patienten mit DFS-Ereignissen 7697
Zusammenfassung über das erste Auftreten eines DFS-Ereignisses 7705
Unerwünschte Ereignisse die zum Tode führen 7707
Unerwünschtes Ereignis: Diarrhö 7710
Verteilung der Patienten pro Arm 7713
Follow-up time (UE, SUE, OS, DFS) 7716

Legende für alle Outputs der Studie APHINITY:
Pertuzumab: Pertuzumab + Trastuzumab + Chemotherapie
Placebo: Placebo + Trastuzumab + Chemotherapie

Endpunkte der Studie APHINITY

Wirksamkeit (Datenschnitt: 19.12.2016)

Time-to-Event (TTE) Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	72	4,0	1739	96,0	NE	NE	NE	NE	NE	NE	1823	100,0	80	4,4	1743	95,6	NE	NE	NE	NE	NE	NE	0,4856	0,89	0,65	1,23		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_OS_ST.xls
10AUG2020 13:59

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	166	9,2	1645	90,8	NE	NE	NE	NE	NE	NE	1823	100,0	211	11,6	1612	88,4	NE	NE	NE	NE	NE	NE	0,0188	0,78	0,64	0,96		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DFS_ST.xls
10AUG2020 14:09

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival - Time to recurrence
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	150	8,3	1661	91,7	NE	NE	NE	NE	NE	NE	1823	100,0	197	10,8	1626	89,2	NE	NE	NE	NE	NE	NE	0,0099	0,76	0,61	0,94		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DFSREC_ST.xls
10AUG2020 14:18

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival - Time to death
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	16	0,9	1795	99,1	NE	NE	NE	NE	NE	NE	1823	100,0	14	0,8	1809	99,2	NE	NE	NE	NE	NE	NE	0,6598	1,17	0,57	2,41		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DFSDTH_ST.xls
10AUG2020 14:25

POPULATION: HR negative or node positive ITT
ENDPOINT: Invasive disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	150	8,3	1661	91,7	NE	NE	NE	NE	NE	NE	1823	100,0	192	10,5	1631	89,5	NE	NE	NE	NE	NE	NE	0,0210	0,78	0,63	0,96		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_IDFS_ST.xls
10AUG2020 13:46

POPULATION: HR negative or node positive ITT
ENDPOINT: Invasive disease-free survival including second primary non-breast cancer
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	163	9,0	1648	91,0	NE	NE	NE	NE	NE	NE	1823	100,0	205	11,2	1618	88,8	NE	NE	NE	NE	NE	NE	0,0254	0,79	0,64	0,97		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_IDFSS_ST.xls
10AUG2020 13:52

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	108	6,0	1703	94,0	NE	NE	NE	NE	NE	NE	1823	100,0	137	7,5	1686	92,5	NE	NE	NE	NE	NE	NE	0,0551	0,78	0,61	1,01		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DRFI_ST.xls
10AUG2020 13:25

Wirksamkeit (Datenschnitt: 19.12.2016)

Time-to-Event (TTE) Analysen

Subgruppen

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	72	4,0	1739	96,0	NE	NE	NE	NE	NE	NE	1823	100,0	80	4,4	1743	95,6	NE	NE	NE	NE	NE	NE	0,5534	0,91	0,66	1,25		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	2	3,9	49	96,1	NE	NE	NE	NE	NE	NE	43	2,4	0	0,0	43	100,0	NE	NE	NE	NE	NE	NE	0,1908	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	4	1,6	253	98,4	NE	NE	NE	NE	NE	NE	278	15,2	2	0,7	276	99,3	NE	NE	NE	NE	NE	NE	0,3722	2,13	0,39	11,61		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	26	2,9	881	97,1	NE	NE	NE	NE	NE	NE	900	49,4	31	3,4	869	96,6	NE	NE	NE	NE	NE	NE	0,5276	0,85	0,50	1,42		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	40	6,7	556	93,3	NE	NE	NE	NE	NE	NE	602	33,0	47	7,8	555	92,2	NE	NE	NE	NE	NE	NE	0,4542	0,85	0,56	1,30		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	58	4,0	1381	96,0	NE	NE	NE	NE	NE	NE	1448	79,4	65	4,5	1383	95,5	NE	NE	NE	NE	NE	NE	0,5616	0,90	0,63	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,9123
	Non-anthracycline	372	20,5	14	3,8	358	96,2	NE	NE	NE	NE	NE	NE	375	20,6	15	4,0	360	96,0	NE	NE	NE	NE	NE	NE	0,8645	0,94	0,45	1,94		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	45	5,2	819	94,8	NE	NE	NE	NE	NE	NE	858	47,1	47	5,5	811	94,5	NE	NE	NE	NE	NE	NE	0,7633	0,94	0,62	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,7660
	Positive (ER and/or PgR positive)	947	52,3	27	2,9	920	97,1	NE	NE	NE	NE	NE	NE	965	52,9	33	3,4	932	96,6	NE	NE	NE	NE	NE	NE	0,5215	0,85	0,51	1,41		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	8	3,0	257	97,0	NE	NE	NE	NE	NE	NE	260	14,3	7	2,7	253	97,3	NE	NE	NE	NE	NE	NE	0,8282	1,12	0,41	3,08		Convergence criterion (GCONV=1E-8) satisfied.	-
	Western Europe	827	45,7	34	4,1	793	95,9	NE	NE	NE	NE	NE	NE	822	45,1	33	4,0	789	96,0	NE	NE	NE	NE	NE	NE	0,8750	1,04	0,64	1,68		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	23	4,7	467	95,3	NE	NE	NE	NE	NE	NE	512	28,1	19	3,7	493	96,3	NE	NE	NE	NE	NE	NE	0,4514	1,26	0,69	2,32		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Latin America	43	2,4	1	2,3	42	97,7	NE	NE	NE	NE	NE	NE	47	2,6	4	8,5	43	91,5	53,7	53,7	NE	53,7	53,7	NE	0,2473	0,29	0,03	2,66		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	186	10,3	6	3,2	180	96,8	NE	52,3	NE	NE	NE	NE	182	10,0	17	9,3	165	90,7	NE	NE	NE	NE	NE	NE	0,0186	0,34	0,14	0,87		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	54	4,4	1186	95,6	NE	NE	NE	NE	NE	NE	1246	68,3	53	4,3	1193	95,7	NE	NE	NE	NE	NE	NE	0,8841	1,03	0,70	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,2360
	Protocol amendment B	571	31,5	18	3,2	553	96,8	NE	NE	NE	NE	NE	NE	577	31,7	27	4,7	550	95,3	NE	NE	NE	NE	NE	NE	0,1853	0,67	0,37	1,22		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	6	1,9	302	98,1	NE	NE	NE	NE	NE	NE	321	17,6	2	0,6	319	99,4	NE	NE	NE	NE	NE	NE	0,1441	3,10	0,63	15,36		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 1 positive nodes	1503	83,0	66	4,4	1437	95,6	NE	NE	NE	NE	NE	NE	1502	82,4	78	5,2	1424	94,8	NE	NE	NE	NE	NE	NE	0,3325	0,85	0,61	1,18		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	30	3,4	843	96,6	NE	NE	NE	NE	NE	NE	885	48,5	23	2,6	862	97,4	NE	NE	NE	NE	NE	NE	0,3019	1,33	0,77	2,29		Convergence criterion (GCONV=1E-8) satisfied.	0,0814
	Postmenopausal	933	51,5	42	4,5	891	95,5	NE	NE	NE	NE	NE	NE	929	51,0	57	6,1	872	93,9	NE	NE	NE	NE	NE	NE	0,1250	0,73	0,49	1,09		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	0	0,0	9	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	56	3,5	1525	96,5	NE	NE	NE	NE	NE	NE	1604	88,0	63	3,9	1541	96,1	NE	NE	NE	NE	NE	NE	0,5629	0,90	0,63	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,9173
	>= 65	230	12,7	16	7,0	214	93,0	NE	NE	NE	NE	NE	NE	219	12,0	17	7,8	202	92,2	NE	53,7	NE	NE	NE	NE	0,8669	0,94	0,48	1,87		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	0	0,0	32	100,0	NE	NE	NE	NE	NE	NE	24	1,3	1	4,2	23	95,8	NE	NE	NE	NE	NE	NE	0,2557	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	19	3,4	533	96,6	NE	NE	NE	NE	NE	NE	557	30,6	21	3,8	536	96,2	NE	NE	NE	NE	NE	NE	0,7782	0,91	0,49	1,70		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	49	4,2	1112	95,8	NE	NE	NE	NE	NE	NE	1173	64,3	54	4,6	1119	95,4	NE	NE	NE	NE	NE	NE	0,6697	0,92	0,62	1,35		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	4	6,1	62	93,9	NE	NE	NE	NE	NE	NE	69	3,8	4	5,8	65	94,2	NE	NE	NE	NE	NE	NE	0,9713	1,03	0,26	4,10		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	15	2,1	713	97,9	NE	NE	NE	NE	NE	NE	715	39,2	21	2,9	694	97,1	NE	NE	NE	NE	NE	NE	0,2692	0,69	0,36	1,34		Convergence criterion (GCONV=1E-8) satisfied.	0,3173
	Mastectomy	1083	59,8	57	5,3	1026	94,7	NE	NE	NE	NE	NE	NE	1107	60,7	59	5,3	1048	94,7	NE	NE	NE	NE	NE	NE	0,9658	1,01	0,70	1,45		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	18	2,7	642	97,3	NE	NE	NE	NE	NE	NE	665	36,5	24	3,6	641	96,4	NE	NE	NE	NE	NE	NE	0,3633	0,75	0,41	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,7130
	>= 2 - < 5 cm	1009	55,7	42	4,2	967	95,8	NE	NE	NE	NE	NE	NE	991	54,4	43	4,3	948	95,7	NE	NE	NE	NE	NE	NE	0,8428	0,96	0,63	1,47		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	12	8,6	127	91,4	NE	NE	NE	NE	NE	NE	165	9,1	13	7,9	152	92,1	NE	NE	NE	NE	NE	NE	0,7830	1,12	0,51	2,45		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	42	3,1	1305	96,9	NE	NE	NE	NE	NE	NE	1350	74,1	54	4,0	1296	96,0	NE	NE	NE	NE	NE	NE	0,2104	0,77	0,52	1,16		Convergence criterion (GCONV=1E-8) satisfied.	0,1736
	No	464	25,6	30	6,5	434	93,5	NE	NE	NE	NE	NE	NE	473	25,9	26	5,5	447	94,5	NE	NE	NE	NE	NE	NE	0,4533	1,22	0,72	2,07		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	48	3,8	1204	96,2	NE	NE	NE	NE	NE	NE	1255	68,8	58	4,6	1197	95,4	NE	NE	NE	NE	NE	NE	0,3446	0,83	0,57	1,22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	1	4,0	24	96,0	NE	NE	NE	NE	NE	NE	31	1,7	0	0,0	31	100,0	NE	NE	NE	NE	NE	NE	0,2429	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	22	4,6	455	95,4	NE	NE	NE	NE	NE	NE	484	26,5	18	3,7	466	96,3	NE	NE	NE	NE	NE	NE	0,4881	1,25	0,67	2,32		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	1	1,9	51	98,1	NE	NE	NE	NE	NE	NE	51	2,8	4	7,8	47	92,2	53,7	53,7	NE	NE	53,7	NE	0,2244	0,28	0,03	2,53		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_OS_SG.xls
10AUG2020 14:06

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	166	9,2	1645	90,8	NE	NE	NE	NE	NE	NE	1823	100,0	211	11,6	1612	88,4	NE	NE	NE	NE	NE	NE	0,0225	0,79	0,64	0,97		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	3	5,9	48	94,1	NE	NE	NE	NE	NE	NE	43	2,4	4	9,3	39	90,7	NE	49,0	NE	NE	NE	NE	0,4770	0,58	0,13	2,62		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	11	4,3	246	95,7	NE	NE	NE	NE	NE	NE	278	15,2	10	3,6	268	96,4	NE	NE	NE	NE	NE	NE	0,7316	1,16	0,49	2,74		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	62	6,8	845	93,2	NE	NE	NE	NE	NE	NE	900	49,4	85	9,4	815	90,6	NE	NE	NE	NE	NE	NE	0,0563	0,73	0,52	1,01		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	90	15,1	506	84,9	NE	52,6	NE	NE	NE	NE	602	33,0	112	18,6	490	81,4	NE	48,3	NE	NE	NE	NE	0,1205	0,80	0,61	1,06		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	135	9,4	1304	90,6	NE	NE	NE	NE	NE	NE	1448	79,4	173	11,9	1275	88,1	NE	NE	NE	NE	NE	NE	0,0325	0,78	0,62	0,98		Convergence criterion (GCONV=1E-8) satisfied.	0,8599
	Non-anthracycline	372	20,5	31	8,3	341	91,7	NE	NE	NE	NE	NE	NE	375	20,6	38	10,1	337	89,9	NE	NE	NE	NE	NE	NE	0,4138	0,82	0,51	1,32		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	82	9,5	782	90,5	NE	NE	NE	NE	NE	NE	858	47,1	100	11,7	758	88,3	NE	NE	NE	NE	NE	NE	0,1370	0,80	0,60	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,8969
	Positive (ER and/or PgR positive)	947	52,3	84	8,9	863	91,1	NE	NE	NE	NE	NE	NE	965	52,9	111	11,5	854	88,5	NE	NE	NE	NE	NE	NE	0,0839	0,78	0,59	1,03		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	20	7,5	245	92,5	NE	NE	NE	NE	NE	NE	260	14,3	22	8,5	238	91,5	NE	NE	NE	NE	NE	NE	0,6851	0,88	0,48	1,62		Convergence criterion (GCONV=1E-8) satisfied.	0,6686
	Western Europe	827	45,7	79	9,6	748	90,4	NE	NE	NE	NE	NE	NE	822	45,1	92	11,2	730	88,8	NE	NE	NE	NE	NE	NE	0,3263	0,86	0,64	1,16		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	45	9,2	445	90,8	NE	NE	NE	NE	NE	NE	512	28,1	59	11,5	453	88,5	NE	NE	NE	NE	NE	NE	0,2432	0,79	0,54	1,17		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	4	9,3	39	90,7	NE	NE	NE	NE	NE	NE	47	2,6	10	21,3	37	78,7	53,7	35,0	NE	53,7	53,7	NE	0,1523	0,44	0,14	1,40		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	18	9,7	168	90,3	NE	NE	NE	NE	NE	NE	182	10,0	28	15,4	154	84,6	NE	NE	NE	NE	NE	NE	0,1093	0,62	0,34	1,12		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	112	9,0	1128	91,0	NE	NE	NE	NE	NE	NE	1246	68,3	136	10,9	1110	89,1	NE	NE	NE	NE	NE	NE	0,1296	0,82	0,64	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,5712
	Protocol amendment B	571	31,5	54	9,5	517	90,5	NE	NE	NE	NE	NE	NE	577	31,7	75	13,0	502	87,0	NE	NE	NE	NE	NE	NE	0,0717	0,73	0,51	1,03		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	14	4,5	294	95,5	NE	NE	NE	NE	NE	NE	321	17,6	14	4,4	307	95,6	NE	NE	NE	NE	NE	NE	0,9571	1,02	0,49	2,14		Convergence criterion (GCONV=1E-8) satisfied.	0,4722
	>= 1 positive nodes	1503	83,0	152	10,1	1351	89,9	NE	NE	NE	NE	NE	NE	1502	82,4	197	13,1	1305	86,9	NE	NE	NE	NE	NE	NE	0,0157	0,77	0,62	0,95		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	88	10,1	785	89,9	NE	NE	NE	NE	NE	NE	885	48,5	97	11,0	788	89,0	NE	NE	NE	NE	NE	NE	0,5635	0,92	0,69	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,1735
	Postmenopausal	933	51,5	78	8,4	855	91,6	NE	NE	NE	NE	NE	NE	929	51,0	112	12,1	817	87,9	NE	NE	NE	NE	NE	NE	0,0119	0,69	0,52	0,92		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	2	22,2	7	77,8	51,0	25,8	51,0	51,0	NE	NE	0,2048	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	142	9,0	1439	91,0	NE	NE	NE	NE	NE	NE	1604	88,0	178	11,1	1426	88,9	NE	NE	NE	NE	NE	NE	0,0508	0,80	0,64	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,6932
	>= 65	230	12,7	24	10,4	206	89,6	NE	NE	NE	NE	NE	NE	219	12,0	33	15,1	186	84,9	NE	53,7	NE	NE	NE	NE	0,2127	0,72	0,42	1,21		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	24	1,3	3	12,5	21	87,5	NE	44,2	NE	NE	NE	NE	0,2470	0,29	0,03	2,75		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	41	7,4	511	92,6	NE	NE	NE	NE	NE	NE	557	30,6	63	11,3	494	88,7	NE	53,7	NE	NE	NE	NE	0,0318	0,65	0,44	0,97		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	116	10,0	1045	90,0	NE	NE	NE	NE	NE	NE	1173	64,3	138	11,8	1035	88,2	NE	NE	NE	NE	NE	NE	0,1907	0,85	0,66	1,09		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	8	12,1	58	87,9	NE	NE	NE	NE	NE	NE	69	3,8	7	10,1	62	89,9	NE	NE	NE	NE	NE	NE	0,7181	1,20	0,44	3,32		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	45	6,2	683	93,8	NE	NE	NE	NE	NE	NE	715	39,2	64	9,0	651	91,0	NE	NE	NE	NE	NE	NE	0,0412	0,67	0,46	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,3043

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	121	11,2	962	88,8	NE	NE	NE	NE	NE	NE	1107	60,7	147	13,3	960	86,7	NE	NE	NE	NE	NE	NE	0,1950	0,85	0,67	1,09		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	44	6,7	616	93,3	NE	NE	NE	NE	NE	NE	665	36,5	62	9,3	603	90,7	NE	NE	NE	NE	NE	NE	0,0821	0,71	0,48	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,6654
	>= 2 - < 5 cm	1009	55,7	100	9,9	909	90,1	NE	NE	NE	NE	NE	NE	991	54,4	113	11,4	878	88,6	NE	NE	NE	NE	NE	NE	0,2983	0,87	0,66	1,13		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	22	15,8	117	84,2	NE	NE	NE	NE	NE	NE	165	9,1	36	21,8	129	78,2	48,3	41,9	NE	NE	NE	NE	0,2378	0,73	0,43	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	116	8,6	1231	91,4	NE	NE	NE	NE	NE	NE	1350	74,1	154	11,4	1196	88,6	NE	NE	NE	NE	NE	NE	0,0167	0,75	0,59	0,95		Convergence criterion (GCONV=1E-8) satisfied.	0,3648
	No	464	25,6	50	10,8	414	89,2	NE	NE	NE	NE	NE	NE	473	25,9	57	12,1	416	87,9	NE	NE	NE	NE	NE	NE	0,6597	0,92	0,63	1,34		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	117	9,3	1135	90,7	NE	NE	NE	NE	NE	NE	1255	68,8	142	11,3	1113	88,7	NE	NE	NE	NE	NE	NE	0,1234	0,83	0,65	1,05		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	1	4,0	24	96,0	NE	NE	NE	NE	NE	NE	31	1,7	2	6,5	29	93,5	NE	48,3	NE	NE	NE	NE	0,7313	0,66	0,06	7,27		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	44	9,2	433	90,8	NE	NE	NE	NE	NE	NE	484	26,5	55	11,4	429	88,6	NE	NE	NE	NE	NE	NE	0,3013	0,81	0,55	1,21		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	4	7,7	48	92,3	NE	NE	NE	NE	NE	NE	51	2,8	11	21,6	40	78,4	53,7	35,0	NE	NE	53,7	NE	0,0618	0,35	0,11	1,11		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	1	50,0	1	50,0	42,1	42,1	NE	NE	42,1	NE	0,2207	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DFS_SG.xls
10AUG2020 14:15

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	108	6,0	1703	94,0	NE	NE	NE	NE	NE	NE	1823	100,0	137	7,5	1686	92,5	NE	NE	NE	NE	NE	NE	0,0730	0,79	0,62	1,02		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	0	0,0	51	100,0	NE	NE	NE	NE	NE	NE	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	0,0870	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	4	1,6	253	98,4	NE	NE	NE	NE	NE	NE	278	15,2	3	1,1	275	98,9	NE	NE	NE	NE	NE	NE	0,6567	1,40	0,31	6,26		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	34	3,7	873	96,3	NE	NE	NE	NE	NE	NE	900	49,4	45	5,0	855	95,0	NE	NE	NE	NE	NE	NE	0,2217	0,76	0,49	1,18		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	70	11,7	526	88,3	NE	NE	NE	NE	NE	NE	602	33,0	87	14,5	515	85,5	NE	NE	NE	NE	NE	NE	0,1850	0,81	0,59	1,11		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	93	6,5	1346	93,5	NE	NE	NE	NE	NE	NE	1448	79,4	111	7,7	1337	92,3	NE	NE	NE	NE	NE	NE	0,2331	0,85	0,64	1,11		Convergence criterion (GCONV=1E-8) satisfied.	0,2762
	Non-anthracycline	372	20,5	15	4,0	357	96,0	NE	NE	NE	NE	NE	NE	375	20,6	26	6,9	349	93,1	NE	NE	NE	NE	NE	NE	0,0862	0,58	0,31	1,09		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	47	5,4	817	94,6	NE	NE	NE	NE	NE	NE	858	47,1	64	7,5	794	92,5	NE	NE	NE	NE	NE	NE	0,0809	0,72	0,49	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,4530
	Positive (ER and/or PgR positive)	947	52,3	61	6,4	886	93,6	NE	NE	NE	NE	NE	NE	965	52,9	73	7,6	892	92,4	NE	NE	NE	NE	NE	NE	0,4163	0,87	0,62	1,22		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	10	3,8	255	96,2	NE	NE	NE	NE	NE	NE	260	14,3	13	5,0	247	95,0	NE	NE	NE	NE	NE	NE	0,5037	0,76	0,33	1,72		Convergence criterion (GCONV=1E-8) satisfied.	-
	Western Europe	827	45,7	54	6,5	773	93,5	NE	NE	NE	NE	NE	NE	822	45,1	60	7,3	762	92,7	NE	NE	NE	NE	NE	NE	0,5832	0,90	0,62	1,30		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	26	5,3	464	94,7	NE	NE	NE	NE	NE	NE	512	28,1	39	7,6	473	92,4	NE	NE	NE	NE	NE	NE	0,1470	0,69	0,42	1,14		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	3	7,0	40	93,0	NE	NE	NE	NE	NE	NE	47	2,6	6	12,8	41	87,2	NE	NE	NE	NE	NE	NE	0,3697	0,54	0,13	2,14		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	15	8,1	171	91,9	NE	NE	NE	NE	NE	NE	182	10,0	19	10,4	163	89,6	NE	NE	NE	NE	NE	NE	0,4475	0,77	0,39	1,51		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	69	5,6	1171	94,4	NE	NE	NE	NE	NE	NE	1246	68,3	84	6,7	1162	93,3	NE	NE	NE	NE	NE	NE	0,2378	0,83	0,60	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,7025
	Protocol amendment B	571	31,5	39	6,8	532	93,2	NE	NE	NE	NE	NE	NE	577	31,7	53	9,2	524	90,8	NE	NE	NE	NE	NE	NE	0,1613	0,74	0,49	1,13		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	4	1,3	304	98,7	NE	NE	NE	NE	NE	NE	321	17,6	5	1,6	316	98,4	NE	NE	NE	NE	NE	NE	0,7608	0,82	0,22	3,04		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 1 positive nodes	1503	83,0	104	6,9	1399	93,1	NE	NE	NE	NE	NE	NE	1502	82,4	132	8,8	1370	91,2	NE	NE	NE	NE	NE	NE	0,0738	0,79	0,61	1,02		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	66	7,6	807	92,4	NE	NE	NE	NE	NE	NE	885	48,5	65	7,3	820	92,7	NE	NE	NE	NE	NE	NE	0,8364	1,04	0,74	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,0251
	Postmenopausal	933	51,5	42	4,5	891	95,5	NE	NE	NE	NE	NE	NE	929	51,0	72	7,8	857	92,2	NE	NE	NE	NE	NE	NE	0,0044	0,58	0,40	0,85		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	0	0,0	9	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	97	6,1	1484	93,9	NE	NE	NE	NE	NE	NE	1604	88,0	118	7,4	1486	92,6	NE	NE	NE	NE	NE	NE	0,1767	0,83	0,64	1,09		Convergence criterion (GCONV=1E-8) satisfied.	0,3409
	>= 65	230	12,7	11	4,8	219	95,2	NE	NE	NE	NE	NE	NE	219	12,0	19	8,7	200	91,3	NE	NE	NE	NE	NE	NE	0,1281	0,57	0,27	1,19		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	24	1,3	2	8,3	22	91,7	NE	NE	NE	NE	NE	NE	0,4485	0,41	0,04	4,50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	24	4,3	528	95,7	NE	NE	NE	NE	NE	NE	557	30,6	38	6,8	519	93,2	NE	NE	NE	NE	NE	NE	0,0855	0,64	0,38	1,07		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	78	6,7	1083	93,3	NE	NE	NE	NE	NE	NE	1173	64,3	94	8,0	1079	92,0	NE	NE	NE	NE	NE	NE	0,2497	0,84	0,62	1,13		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	5	7,6	61	92,4	NE	NE	NE	NE	NE	NE	69	3,8	3	4,3	66	95,7	NE	NE	NE	NE	NE	NE	0,4517	1,72	0,41	7,20		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	23	3,2	705	96,8	NE	NE	NE	NE	NE	NE	715	39,2	35	4,9	680	95,1	NE	NE	NE	NE	NE	NE	0,0853	0,63	0,37	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,2968

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	85	7,8	998	92,2	NE	NE	NE	NE	NE	NE	1107	60,7	102	9,2	1005	90,8	NE	NE	NE	NE	NE	NE	0,3327	0,87	0,65	1,16		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	21	3,2	639	96,8	NE	NE	NE	NE	NE	NE	665	36,5	36	5,4	629	94,6	NE	NE	NE	NE	NE	NE	0,0460	0,58	0,34	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,3154
	>= 2 - < 5 cm	1009	55,7	67	6,6	942	93,4	NE	NE	NE	NE	NE	NE	991	54,4	78	7,9	913	92,1	NE	NE	NE	NE	NE	NE	0,3200	0,85	0,61	1,18		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	20	14,4	119	85,6	NE	NE	NE	NE	NE	NE	165	9,1	23	13,9	142	86,1	NE	48,8	NE	NE	NE	NE	0,8497	1,06	0,58	1,93		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	85	6,3	1262	93,7	NE	NE	NE	NE	NE	NE	1350	74,1	104	7,7	1246	92,3	NE	NE	NE	NE	NE	NE	0,1570	0,81	0,61	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,7298
	No	464	25,6	23	5,0	441	95,0	NE	NE	NE	NE	NE	NE	473	25,9	33	7,0	440	93,0	NE	NE	NE	NE	NE	NE	0,2433	0,73	0,43	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	78	6,2	1174	93,8	NE	NE	NE	NE	NE	NE	1255	68,8	95	7,6	1160	92,4	NE	NE	NE	NE	NE	NE	0,2044	0,82	0,61	1,11		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	1	4,0	24	96,0	NE	NE	NE	NE	NE	NE	31	1,7	1	3,2	30	96,8	NE	48,8	NE	NE	NE	NE	0,8785	1,24	0,08	19,89		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	26	5,5	451	94,5	NE	NE	NE	NE	NE	NE	484	26,5	35	7,2	449	92,8	NE	NE	NE	NE	NE	NE	0,2779	0,76	0,45	1,26		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	3	5,8	49	94,2	NE	NE	NE	NE	NE	NE	51	2,8	6	11,8	45	88,2	NE	NE	NE	NE	NE	NE	0,2738	0,47	0,12	1,88		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

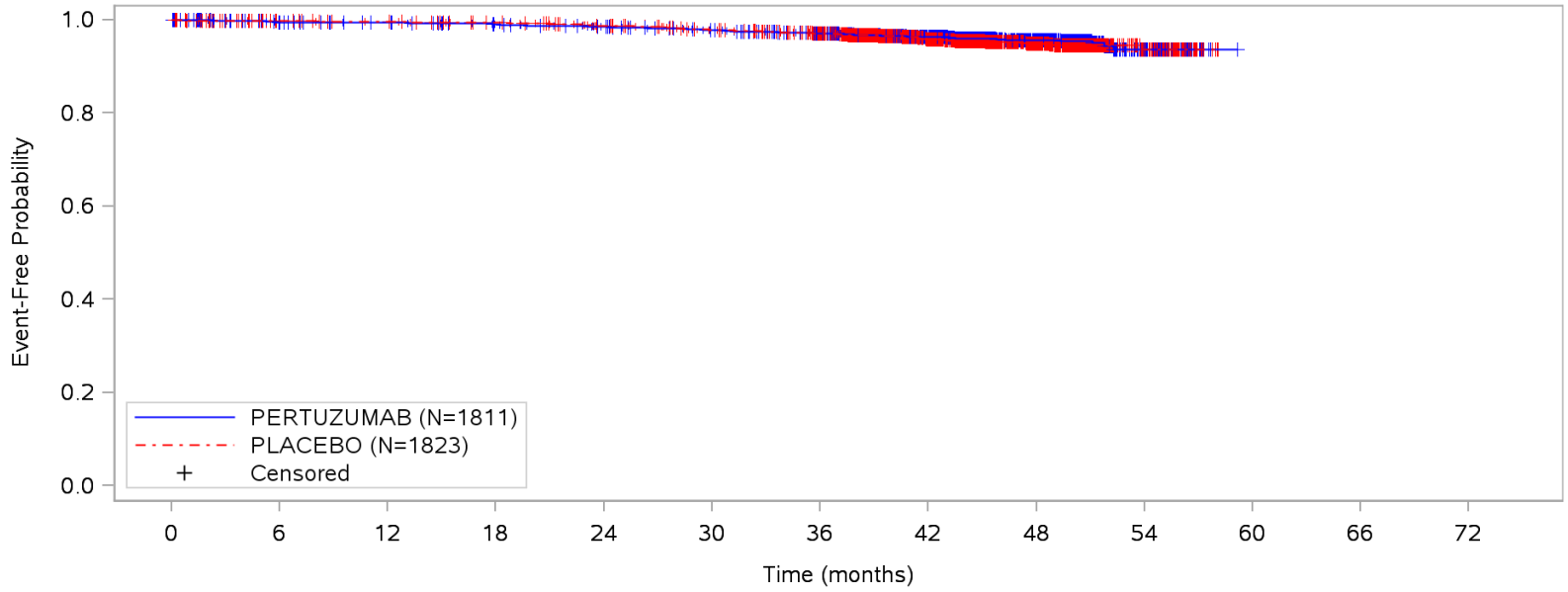
Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_26a_19DEC2016_CHON_DRFI_SG.xls
10AUG2020 13:27

Wirksamkeit (Datenschnitt: 19.12.2016)

Time-to-Event (TTE) Analysen

KM Plots

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Overall survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

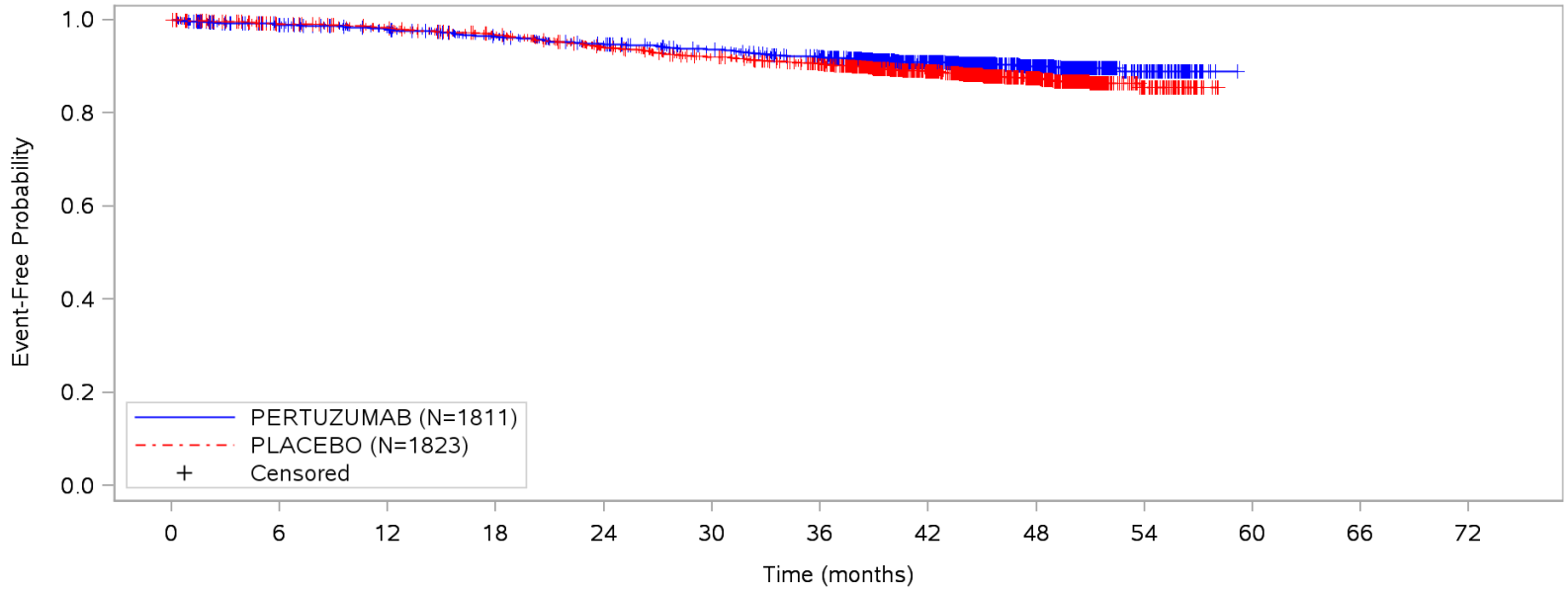


Patients at risk													
PERTUZUMAB	1811	1754	1740	1722	1706	1682	1641	1235	599	94	NE	NE	NE
PLACEBO	1823	1780	1771	1753	1731	1704	1652	1219	591	82	NE	NE	NE
Patients censored													
PERTUZUMAB	0	47	60	72	78	91	121	515	1144	1645	NE	NE	NE
PLACEBO	0	39	46	59	69	82	121	536	1162	1661	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_OS.pdf
16JUL2020 17:06

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

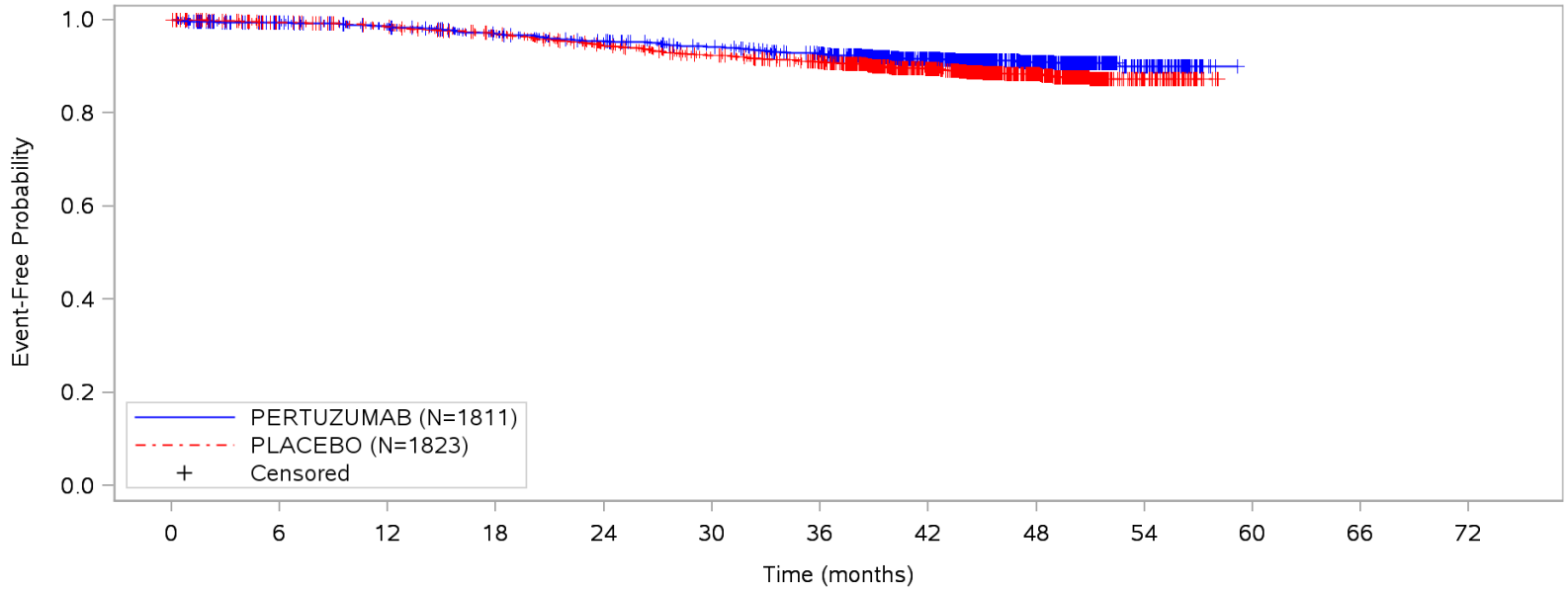


Patients at risk													
PERTUZUMAB	1811	1742	1713	1675	1642	1608	1560	1180	579	93	NE	NE	NE
PLACEBO	1823	1766	1742	1704	1649	1603	1544	1150	558	78	NE	NE	NE
Patients censored													
PERTUZUMAB	0	51	64	73	78	93	113	476	1069	1552	NE	NE	NE
PLACEBO	0	42	51	63	70	80	113	483	1066	1534	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_DFS.pdf
16JUL2020 17:08

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival - Time to recurrence
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

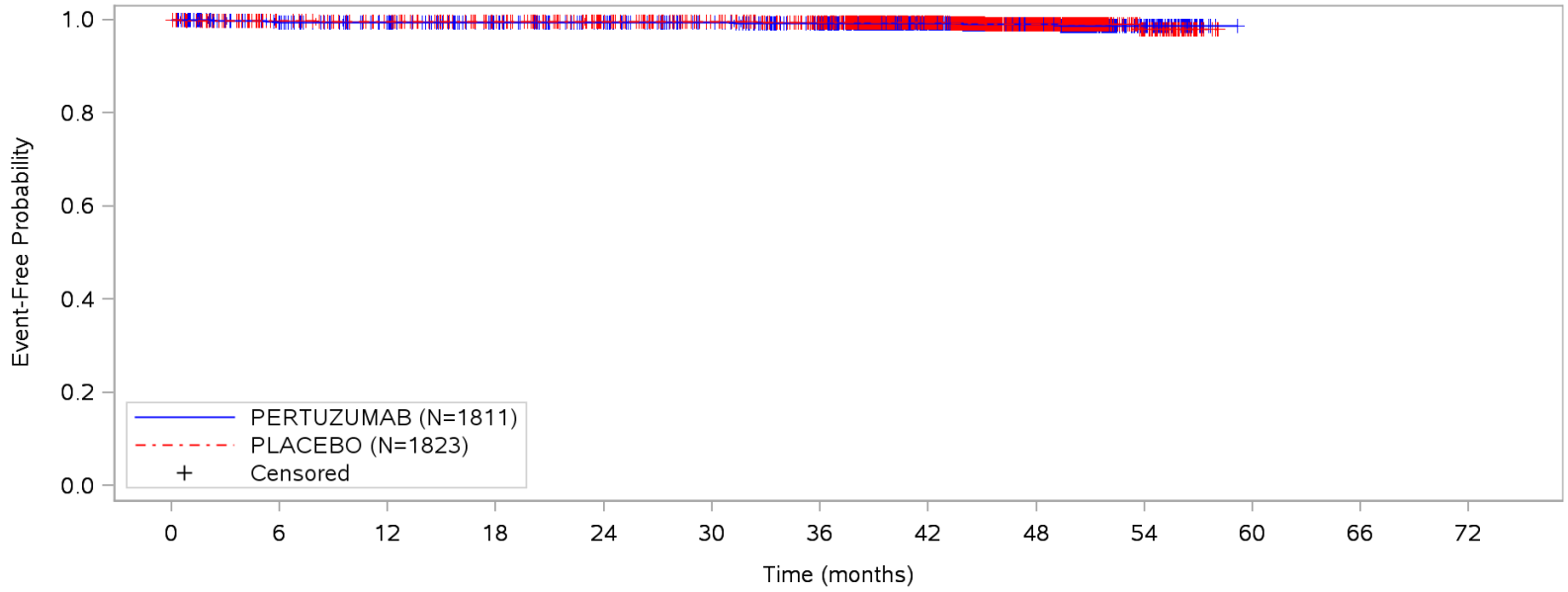


Patients at risk													
PERTUZUMAB	1811	1742	1713	1675	1642	1608	1560	1180	579	93	NE	NE	NE
PLACEBO	1823	1766	1742	1704	1649	1603	1544	1150	558	78	NE	NE	NE
Patients censored													
PERTUZUMAB	0	60	74	84	89	104	126	489	1084	1568	NE	NE	NE
PLACEBO	0	46	56	68	77	87	121	493	1079	1548	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_DFSREC.pdf
16JUL2020 17:09

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival - Time to death
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

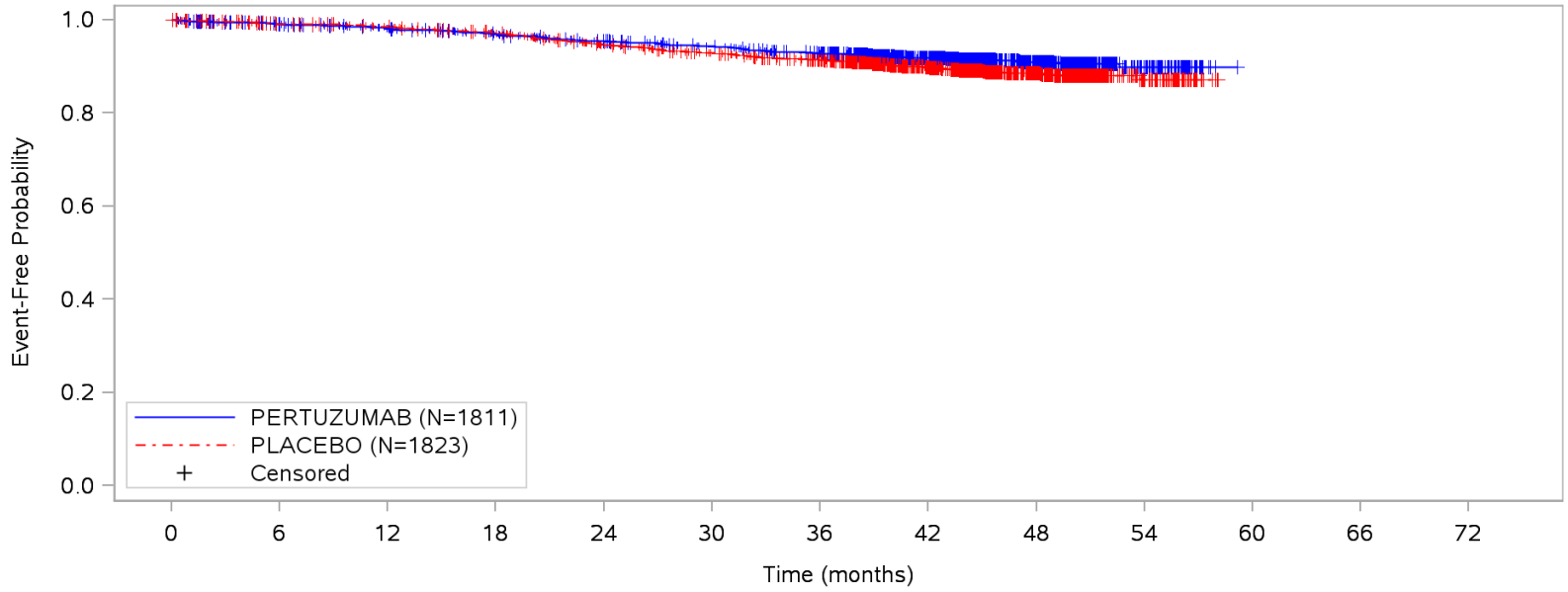


Patients at risk													
PERTUZUMAB	1811	1742	1713	1675	1642	1608	1560	1180	579	93	NE	NE	NE
PLACEBO	1823	1766	1742	1704	1649	1603	1544	1150	558	78	NE	NE	NE
Patients censored													
PERTUZUMAB	0	60	88	125	158	192	238	618	1217	1702	NE	NE	NE
PLACEBO	0	53	76	114	167	213	271	663	1258	1731	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_DFSDTH.pdf
16JUL2020 17:10

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Invasive disease-free survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

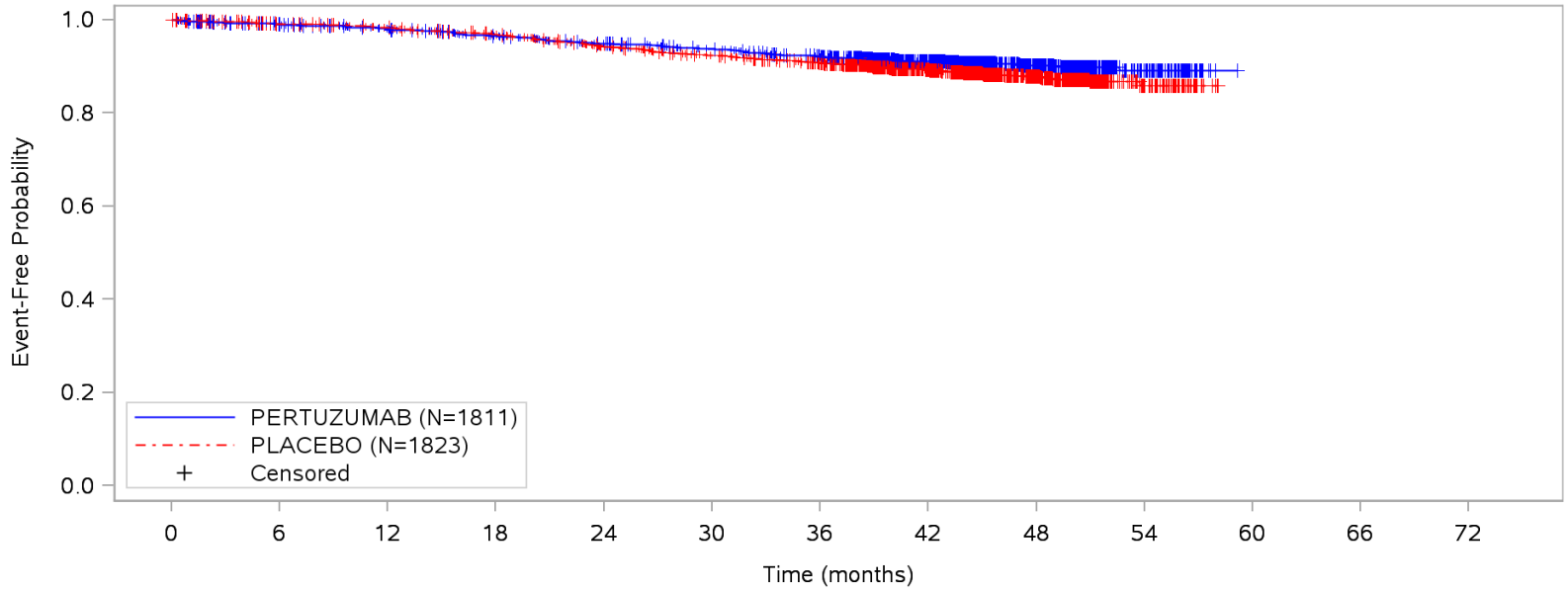


Patients at risk													
PERTUZUMAB	1811	1743	1715	1683	1651	1615	1569	1188	583	93	NE	NE	NE
PLACEBO	1823	1766	1746	1711	1658	1615	1557	1155	560	79	NE	NE	NE
Patients censored													
PERTUZUMAB	0	52	65	74	81	97	117	484	1081	1568	NE	NE	NE
PLACEBO	0	42	51	63	70	82	116	493	1081	1552	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_IDFS.pdf
16JUL2020 17:04

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Invasive disease-free survival including second primary non-breast cancer
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

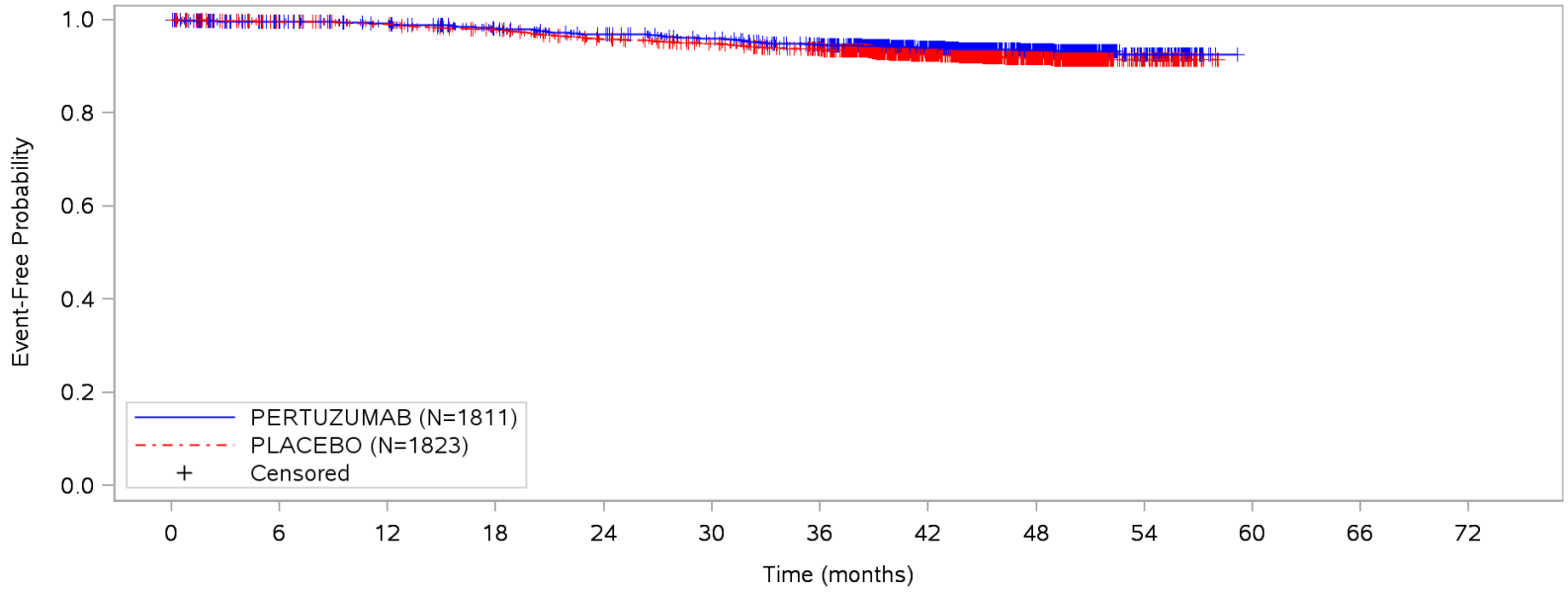


Patients at risk													
PERTUZUMAB	1811	1743	1714	1677	1644	1610	1562	1182	580	93	NE	NE	NE
PLACEBO	1823	1766	1743	1705	1651	1609	1549	1153	559	78	NE	NE	NE
Patients censored													
PERTUZUMAB	0	51	64	73	78	93	113	477	1071	1555	NE	NE	NE
PLACEBO	0	42	51	63	70	80	113	485	1071	1540	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_IDFSS.pdf
16JUL2020 17:05

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)



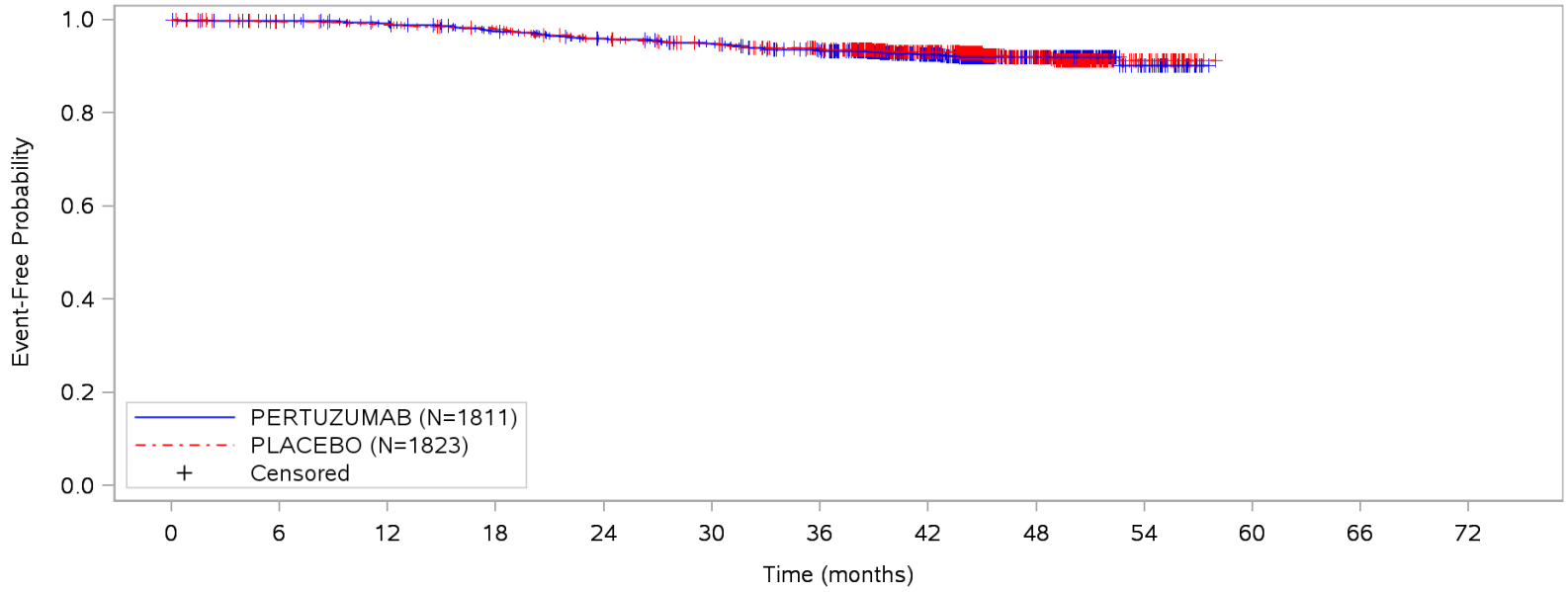
Patients at risk													
PERTUZUMAB	1811	1750	1728	1696	1669	1638	1586	1199	588	94	NE	NE	NE
PLACEBO	1823	1774	1757	1725	1679	1646	1589	1176	569	79	NE	NE	NE
Patients censored													
PERTUZUMAB	0	56	70	83	90	104	133	511	1117	1609	NE	NE	NE
PLACEBO	0	42	50	61	71	88	124	519	1125	1607	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_26a_19DEC2016_CHON_DRFI.pdf
16JUL2020 17:12

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months) by subgroup

Subgroup: Menopausal status at randomization: Premenopausal



Patients at risk													
PERTUZUMAB	873	859	848	829	812	798	768	574	281	41	NE	NE	NE
PLACEBO	885	868	862	851	829	811	786	575	277	39	NE	NE	NE
Patients censored													
PERTUZUMAB	0	13	19	24	27	32	50	237	527	766	NE	NE	NE
PLACEBO	0	13	15	18	21	30	46	251	547	781	NE	NE	NE

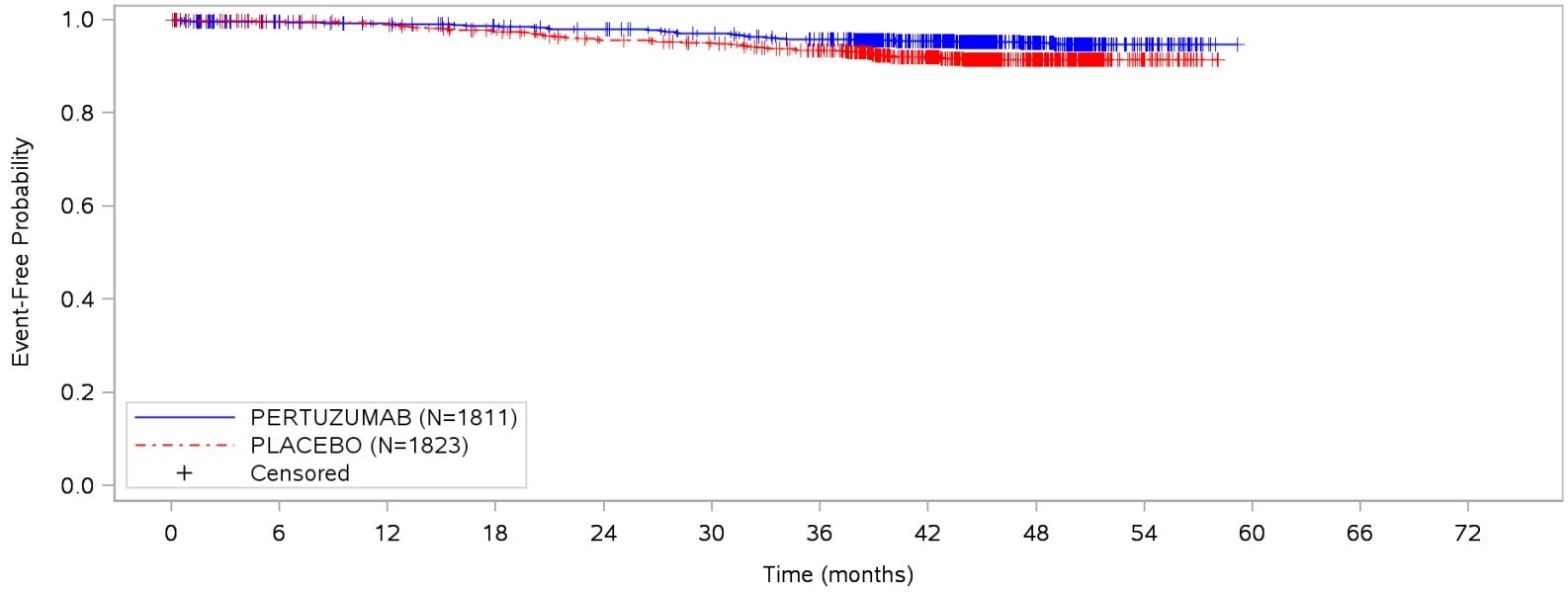
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/getk.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/getk_26a_19DEC2016_CHON_DRFI.pdf
10AUG2020 13:34

Page 1 of 3

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months) by subgroup

Subgroup: Menopausal status at randomization: Postmenopausal



Patients at risk													
PERTUZUMAB	933	886	875	862	852	835	813	621	305	53	NE	NE	NE
PLACEBO	929	897	886	865	841	827	795	594	288	39	NE	NE	NE
Patients censored													
PERTUZUMAB	0	43	51	59	63	72	83	273	587	838	NE	NE	NE
PLACEBO	0	29	35	43	50	57	77	266	573	818	NE	NE	NE

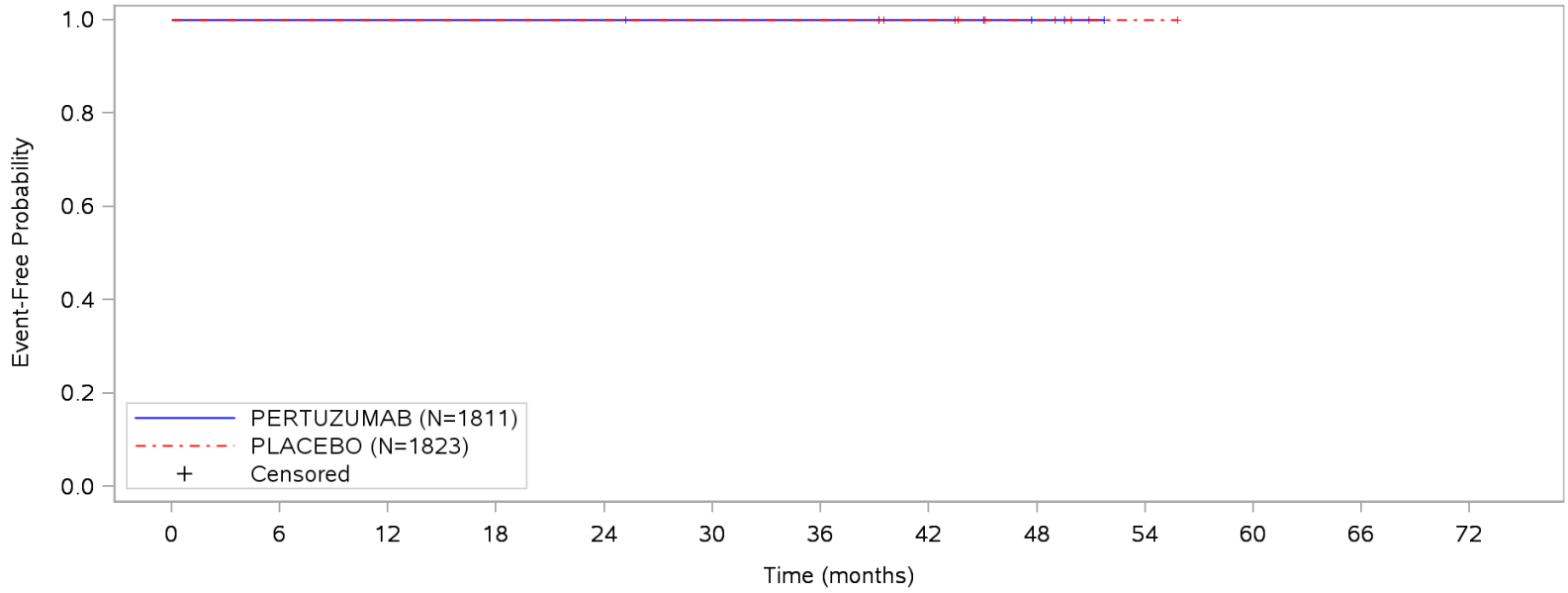
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/getk.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/getk_26a_19DEC2016_CHON_DRFI.pdf
10AUG2020 13:34

Page 2 of 3

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months) by subgroup

Subgroup: Menopausal status at randomization: Unknown/Missing



Patients at risk													
PERTUZUMAB	5	5	5	5	5	5	5	4	2	NE	NE	NE	NE
PLACEBO	9	9	9	9	9	8	8	7	4	1	NE	NE	NE
Patients censored													
PERTUZUMAB	0	0	0	0	0	0	0	1	3	NE	NE	NE	NE
PLACEBO	0	0	0	0	0	1	1	2	5	8	NE	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/getk.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/getk_26a_19DEC2016_CHON_DRFI.pdf
10AUG2020 13:34

Page 3 of 3

Wirksamkeit (Datenschnitt: 19.12.2016)

Responder Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Recurrence/death rate
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Dichotomous analysis (efficacy)

		PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1811	100,0	166	9,2	1823	100,0	211	11,6	0,76		Algorithm converged.	0,61	0,95	-0,018		Algorithm converged.	-0,036	0,000	0,79		Algorithm converged.	0,65	0,95	0,0143	1,27		Algorithm converged.	1,05	1,53

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_resp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_resp_26a_19DEC2016_CHON_RESP1_ST.xls
11AUG2020 14:13

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval rate
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Dichotomous analysis (efficacy)

		PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1811	100,0	108	6,0	1823	100,0	137	7,5	0,77		Algorithm converged.	0,59	1,01	-0,009		Algorithm converged.	-0,023	0,005	0,79		Algorithm converged.	0,62	1,01	0,0567	1,26		Algorithm converged.	0,99	1,60

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_resp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_resp_26a_19DEC2016_CHON_RESP5_ST.xls
11AUG2020 14:18

Wirksamkeit (Datenschnitt: 19.12.2016)

Landmark Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event landmark analysis

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients included in analysis	1811 (100%)		1823 (100%)
Patients with event (%)	166 (9.2%)		211 (11.6%)
Earliest contributing event			
DEATH	16		14
DISEASE RECURRENCE	150		197
Patients without event (%)	1645 (90.8%)		1612 (88.4%)
Time to event (months)			
Median	NE		NE
95% CI	NE		NE
25% and 75%-ile	NE		NE
Range	0.0* - 59.2*		0.0* - 58.1*
Time point analysis			
0.5 year			
Patients remaining at risk	1742		1766
Event free proportion (%)	98,99		99,17
95% CI	(98.52, 99.45)		(98.74, 99.59)
1 year			
Patients remaining at risk	1713		1742
Event free proportion (%)	98,07		98,32
95% CI	(97.43, 98.72)		(97.72, 98.92)
1.5 years			
Patients remaining at risk	1675		1704
Event free proportion (%)	96,41		96,85

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
95% CI	(95.54, 97.28)		(96.04, 97.66)
2 years			
Patients remaining at risk	1642		1649
Event free proportion (%)	94,8		94,11
95% CI	(93.75, 95.84)		(93.02, 95.21)
2.5 years			
Patients remaining at risk	1608		1603
Event free proportion (%)	93,69		92,05
95% CI	(92.55, 94.83)		(90.79, 93.32)
3 years			
Patients remaining at risk	1560		1544
Event free proportion (%)	92,05		90,55
95% CI	(90.78, 93.33)		(89.18, 91.92)
3.5 years			
Patients remaining at risk	1180		1150
Event free proportion (%)	90,94		88,98
95% CI	(89.58, 92.31)		(87.49, 90.46)
4 years			
Patients remaining at risk	579		558
Event free proportion (%)	90,1		87,5
95% CI	(88.62, 91.58)		(85.85, 89.14)
4.5 years			
Patients remaining at risk	93		78
Event free proportion (%)	88,95		85,49
95% CI	(86.77, 91.13)		(82.88, 88.11)

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
5 years			
Patients remaining at risk	NE		NE
Event free proportion (%)	NE		NE
95% CI	NE		NE
5.5 years			
Patients remaining at risk	NE		NE
Event free proportion (%)	NE		NE
95% CI	NE		NE
6 years			
Patients remaining at risk	NE		NE
Event free proportion (%)	NE		NE
95% CI	NE		NE
Stratified analysis			
p-value (log-rank)		0,0188	
Hazard ratio		0,78	
95% CI		(0.64, 0.96)	
Unstratified analysis			
p-value (log-rank)		0,0225	
Hazard ratio		0,79	
95% CI		(0.64, 0.97)	

* Censored observation.
Summaries of time to event (median, percentiles) are based on Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Hazard ratios were estimated by Cox regression.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_lma.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/eff_lma_26a_19DEC2016_CHON_DFS_ST.xls
16JUL2020 17:32

Wirksamkeit (Datenschnitt: 19.06.2019)

Time-to-Event (TTE) Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	108	6,0	1703	94,0	NE	NE	NE	NE	NE	NE	1823	100,0	130	7,1	1693	92,9	NE	NE	NE	NE	NE	NE	0,1360	0,82	0,64	1,06		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_tte_26c_19JUN2019_CHON_OS_ST.xls
10AUG2020 14:58

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	219	12,1	1592	87,9	NE	NE	NE	NE	NE	NE	1823	100,0	287	15,7	1536	84,3	NE	85,9	NE	NE	NE	NE	0,0015	0,75	0,63	0,90		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_tte_26c_19JUN2019_CHON_DFS_ST.xls
10AUG2020 14:46

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	136	7,5	1675	92,5	NE	NE	NE	NE	NE	NE	1823	100,0	180	9,9	1643	90,1	NE	NE	NE	NE	NE	NE	0,0112	0,75	0,60	0,94		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_tte_26c_19JUN2019_CHON_DRFI_ST.xls
10AUG2020 14:52

Wirksamkeit (Datenschnitt: 19.06.2019)

Time-to-Event (TTE) Analysen

Subgruppen

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	108	6,0	1703	94,0	NE	NE	NE	NE	NE	NE	1823	100,0	130	7,1	1693	92,9	NE	NE	NE	NE	NE	NE	0,1661	0,84	0,65	1,08		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	2	3,9	49	96,1	NE	NE	NE	NE	NE	NE	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	0,8723	0,85	0,12	6,05		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	7	2,7	250	97,3	NE	NE	NE	NE	NE	NE	278	15,2	5	1,8	273	98,2	NE	NE	NE	NE	NE	NE	0,4875	1,50	0,48	4,72		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	35	3,9	872	96,1	NE	NE	NE	NE	NE	NE	900	49,4	50	5,6	850	94,4	NE	NE	NE	NE	NE	NE	0,1021	0,70	0,45	1,08		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	64	10,7	532	89,3	NE	NE	NE	NE	NE	NE	602	33,0	73	12,1	529	87,9	NE	81,7	NE	NE	NE	NE	0,4572	0,88	0,63	1,23		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	89	6,2	1350	93,8	NE	NE	NE	NE	NE	NE	1448	79,4	105	7,3	1343	92,7	NE	NE	NE	NE	NE	NE	0,2565	0,85	0,64	1,13		Convergence criterion (GCONV=1E-8) satisfied.	0,7859
	Non-anthracycline	372	20,5	19	5,1	353	94,9	NE	NE	NE	NE	NE	NE	375	20,6	25	6,7	350	93,3	NE	NE	NE	NE	NE	NE	0,3972	0,77	0,43	1,40		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	65	7,5	799	92,5	NE	NE	NE	NE	NE	NE	858	47,1	64	7,5	794	92,5	NE	NE	NE	NE	NE	NE	0,9992	1,00	0,71	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,1257
	Positive (ER and/or PgR positive)	947	52,3	43	4,5	904	95,5	NE	NE	NE	NE	NE	NE	965	52,9	66	6,8	899	93,2	NE	NE	NE	NE	NE	NE	0,0369	0,67	0,45	0,98		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	9	3,4	256	96,6	NE	NE	NE	NE	NE	NE	260	14,3	12	4,6	248	95,4	NE	NE	NE	NE	NE	NE	0,4852	0,74	0,31	1,75		Convergence criterion (GCONV=1E-8) satisfied.	-
	Western Europe	827	45,7	47	5,7	780	94,3	NE	NE	NE	NE	NE	NE	822	45,1	56	6,8	766	93,2	NE	NE	NE	NE	NE	NE	0,3879	0,84	0,57	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	34	6,9	456	93,1	NE	NE	NE	NE	NE	NE	512	28,1	33	6,4	479	93,6	NE	NE	NE	NE	NE	NE	0,8118	1,06	0,66	1,71		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	47	2,6	5	10,6	42	89,4	NE	NE	NE	NE	NE	NE	0,2849	0,42	0,08	2,17		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	16	8,6	170	91,4	NE	NE	NE	NE	NE	NE	182	10,0	24	13,2	158	86,8	81,7	81,7	NE	NE	81,7	NE	0,1675	0,64	0,34	1,21		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	76	6,1	1164	93,9	NE	NE	NE	NE	NE	NE	1246	68,3	86	6,9	1160	93,1	NE	NE	NE	NE	NE	NE	0,4601	0,89	0,65	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,4749
	Protocol amendment B	571	31,5	32	5,6	539	94,4	NE	NE	NE	NE	NE	NE	577	31,7	44	7,6	533	92,4	NE	NE	NE	NE	NE	NE	0,1617	0,72	0,46	1,14		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	9	2,9	299	97,1	NE	NE	NE	NE	NE	NE	321	17,6	7	2,2	314	97,8	NE	NE	NE	NE	NE	NE	0,5718	1,33	0,49	3,57		Convergence criterion (GCONV=1E-8) satisfied.	0,3395
	>= 1 positive nodes	1503	83,0	99	6,6	1404	93,4	NE	NE	NE	NE	NE	NE	1502	82,4	123	8,2	1379	91,8	NE	NE	NE	NE	NE	NE	0,1081	0,81	0,62	1,05		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	45	5,2	828	94,8	NE	NE	NE	NE	NE	NE	885	48,5	44	5,0	841	95,0	NE	NE	NE	NE	NE	NE	0,8518	1,04	0,69	1,58		Convergence criterion (GCONV=1E-8) satisfied.	0,1913
	Postmenopausal	933	51,5	63	6,8	870	93,2	NE	NE	NE	NE	NE	NE	929	51,0	85	9,1	844	90,9	NE	NE	NE	NE	NE	NE	0,0629	0,73	0,53	1,02		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	1	11,1	8	88,9	NE	56,2	NE	NE	NE	NE	0,4292	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	89	5,6	1492	94,4	NE	NE	NE	NE	NE	NE	1604	88,0	104	6,5	1500	93,5	NE	NE	NE	NE	NE	NE	0,3007	0,86	0,65	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,6127
	>= 65	230	12,7	19	8,3	211	91,7	NE	NE	NE	NE	NE	NE	219	12,0	26	11,9	193	88,1	NE	81,6	NE	NE	NE	NE	0,2911	0,73	0,40	1,32		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	0	0,0	32	100,0	NE	NE	NE	NE	NE	NE	24	1,3	3	12,5	21	87,5	NE	60,0	NE	NE	NE	NE	0,0518	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	29	5,3	523	94,7	NE	NE	NE	NE	NE	NE	557	30,6	33	5,9	524	94,1	NE	NE	NE	NE	NE	NE	0,6166	0,88	0,53	1,45		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	75	6,5	1086	93,5	NE	NE	NE	NE	NE	NE	1173	64,3	88	7,5	1085	92,5	NE	NE	NE	NE	NE	NE	0,3407	0,86	0,63	1,17		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	4	6,1	62	93,9	NE	NE	NE	NE	NE	NE	69	3,8	6	8,7	63	91,3	NE	77,6	NE	NE	NE	NE	0,5536	0,68	0,19	2,42		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	25	3,4	703	96,6	NE	NE	NE	NE	NE	NE	715	39,2	35	4,9	680	95,1	NE	NE	NE	NE	NE	NE	0,1552	0,69	0,41	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,3666

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	83	7,7	1000	92,3	NE	NE	NE	NE	NE	NE	1107	60,7	95	8,6	1012	91,4	NE	NE	NE	NE	NE	NE	0,5015	0,90	0,67	1,21		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	23	3,5	637	96,5	NE	NE	NE	NE	NE	NE	665	36,5	38	5,7	627	94,3	NE	NE	NE	NE	NE	NE	0,0547	0,61	0,36	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,3143
	>= 2 - < 5 cm	1009	55,7	67	6,6	942	93,4	NE	NE	NE	NE	NE	NE	991	54,4	68	6,9	923	93,1	NE	NE	NE	NE	NE	NE	0,8534	0,97	0,69	1,36		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	18	12,9	121	87,1	NE	NE	NE	NE	NE	NE	165	9,1	24	14,5	141	85,5	81,7	81,6	NE	NE	NE	NE	0,7443	0,90	0,49	1,66		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	72	5,3	1275	94,7	NE	NE	NE	NE	NE	NE	1350	74,1	93	6,9	1257	93,1	NE	NE	NE	NE	NE	NE	0,0944	0,77	0,57	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,3336
	No	464	25,6	36	7,8	428	92,2	NE	NE	NE	NE	NE	NE	473	25,9	37	7,8	436	92,2	NE	NE	NE	NE	NE	NE	0,9374	1,02	0,64	1,61		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	72	5,8	1180	94,2	NE	NE	NE	NE	NE	NE	1255	68,8	91	7,3	1164	92,7	NE	NE	NE	NE	NE	NE	0,1442	0,79	0,58	1,08		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	1	4,0	24	96,0	NE	NE	NE	NE	NE	NE	31	1,7	1	3,2	30	96,8	NE	NE	NE	NE	NE	NE	0,9281	1,14	0,07	18,39		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	32	6,7	445	93,3	NE	NE	NE	NE	NE	NE	484	26,5	32	6,6	452	93,4	NE	NE	NE	NE	NE	NE	0,9750	1,01	0,62	1,65		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	3	5,8	49	94,2	NE	NE	NE	NE	NE	NE	51	2,8	6	11,8	45	88,2	NE	NE	NE	NE	NE	NE	0,2805	0,47	0,12	1,90		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_tte_26c_19JUN2019_CHON_OS_SG.xls
10AUG2020 15:01

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	136	7,5	1675	92,5	NE	NE	NE	NE	NE	NE	1823	100,0	180	9,9	1643	90,1	NE	NE	NE	NE	NE	NE	0,0148	0,76	0,61	0,95		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	0	0,0	51	100,0	NE	NE	NE	NE	NE	NE	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	0,1229	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	6	2,3	251	97,7	NE	NE	NE	NE	NE	NE	278	15,2	3	1,1	275	98,9	NE	NE	NE	NE	NE	NE	0,2770	2,12	0,53	8,47		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	44	4,9	863	95,1	NE	NE	NE	NE	NE	NE	900	49,4	63	7,0	837	93,0	NE	NE	NE	NE	NE	NE	0,0641	0,70	0,47	1,02		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	86	14,4	510	85,6	NE	NE	NE	NE	NE	NE	602	33,0	112	18,6	490	81,4	NE	76,6	NE	NE	NE	NE	0,0653	0,77	0,58	1,02		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	116	8,1	1323	91,9	NE	NE	NE	NE	NE	NE	1448	79,4	143	9,9	1305	90,1	NE	NE	NE	NE	NE	NE	0,0996	0,81	0,64	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,1817
	Non-anthracycline	372	20,5	20	5,4	352	94,6	NE	NE	NE	NE	NE	NE	375	20,6	37	9,9	338	90,1	NE	NE	NE	NE	NE	NE	0,0259	0,54	0,32	0,94		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	58	6,7	806	93,3	NE	NE	NE	NE	NE	NE	858	47,1	72	8,4	786	91,6	NE	NE	NE	NE	NE	NE	0,1729	0,79	0,56	1,11		Convergence criterion (GCONV=1E-8) satisfied.	0,8159
	Positive (ER and/or PgR positive)	947	52,3	78	8,2	869	91,8	NE	NE	NE	NE	NE	NE	965	52,9	108	11,2	857	88,8	NE	NE	NE	NE	NE	NE	0,0446	0,74	0,56	0,99		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	12	4,5	253	95,5	NE	NE	NE	NE	NE	NE	260	14,3	21	8,1	239	91,9	NE	NE	NE	NE	NE	NE	0,1014	0,56	0,27	1,13		Convergence criterion (GCONV=1E-8) satisfied.	0,8139
	Western Europe	827	45,7	64	7,7	763	92,3	NE	NE	NE	NE	NE	NE	822	45,1	78	9,5	744	90,5	NE	NE	NE	NE	NE	NE	0,2450	0,82	0,59	1,14		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	38	7,8	452	92,2	NE	NE	NE	NE	NE	NE	512	28,1	50	9,8	462	90,2	NE	NE	NE	NE	NE	NE	0,2582	0,78	0,51	1,20		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	3	7,0	40	93,0	NE	NE	NE	NE	NE	NE	47	2,6	7	14,9	40	85,1	NE	56,8	NE	NE	NE	NE	0,2398	0,45	0,12	1,75		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	19	10,2	167	89,8	NE	NE	NE	NE	NE	NE	182	10,0	24	13,2	158	86,8	NE	NE	NE	NE	NE	NE	0,3908	0,77	0,42	1,40		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	82	6,6	1158	93,4	NE	NE	NE	NE	NE	NE	1246	68,3	108	8,7	1138	91,3	NE	NE	NE	NE	NE	NE	0,0627	0,76	0,57	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,9683
	Protocol amendment B	571	31,5	54	9,5	517	90,5	NE	NE	NE	NE	NE	NE	577	31,7	72	12,5	505	87,5	NE	NE	NE	NE	NE	NE	0,1122	0,75	0,53	1,07		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	6	1,9	302	98,1	NE	NE	NE	NE	NE	NE	321	17,6	5	1,6	316	98,4	NE	NE	NE	NE	NE	NE	0,7328	1,23	0,37	4,03		Convergence criterion (GCONV=1E-8) satisfied.	0,4103
	>= 1 positive nodes	1503	83,0	130	8,6	1373	91,4	NE	NE	NE	NE	NE	NE	1502	82,4	175	11,7	1327	88,3	NE	NE	NE	NE	NE	NE	0,0097	0,74	0,59	0,93		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	78	8,9	795	91,1	NE	NE	NE	NE	NE	NE	885	48,5	90	10,2	795	89,8	NE	NE	NE	NE	NE	NE	0,4223	0,88	0,65	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,1652
	Postmenopausal	933	51,5	58	6,2	875	93,8	NE	NE	NE	NE	NE	NE	929	51,0	89	9,6	840	90,4	NE	NE	NE	NE	NE	NE	0,0083	0,64	0,46	0,89		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	1	11,1	8	88,9	NE	49,1	NE	NE	NE	NE	0,4292	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	122	7,7	1459	92,3	NE	NE	NE	NE	NE	NE	1604	88,0	159	9,9	1445	90,1	NE	NE	NE	NE	NE	NE	0,0319	0,77	0,61	0,98		Convergence criterion (GCONV=1E-8) satisfied.	0,6444
	>= 65	230	12,7	14	6,1	216	93,9	NE	NE	NE	NE	NE	NE	219	12,0	21	9,6	198	90,4	NE	NE	NE	NE	NE	NE	0,2137	0,65	0,33	1,28		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	24	1,3	3	12,5	21	87,5	NE	46,2	NE	NE	NE	NE	0,2193	0,27	0,03	2,57		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	33	6,0	519	94,0	NE	NE	NE	NE	NE	NE	557	30,6	52	9,3	505	90,7	NE	NE	NE	NE	NE	NE	0,0389	0,63	0,41	0,98		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	95	8,2	1066	91,8	NE	NE	NE	NE	NE	NE	1173	64,3	122	10,4	1051	89,6	NE	NE	NE	NE	NE	NE	0,0780	0,79	0,60	1,03		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	7	10,6	59	89,4	NE	NE	NE	NE	NE	NE	69	3,8	3	4,3	66	95,7	NE	NE	NE	NE	NE	NE	0,1849	2,42	0,63	9,37		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	31	4,3	697	95,7	NE	NE	NE	NE	NE	NE	715	39,2	46	6,4	669	93,6	NE	NE	NE	NE	NE	NE	0,0583	0,65	0,41	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,3929

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	105	9,7	978	90,3	NE	NE	NE	NE	NE	NE	1107	60,7	134	12,1	973	87,9	NE	NE	NE	NE	NE	NE	0,1077	0,81	0,63	1,05		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	29	4,4	631	95,6	NE	NE	NE	NE	NE	NE	665	36,5	48	7,2	617	92,8	NE	NE	NE	NE	NE	NE	0,0279	0,60	0,38	0,95		Convergence criterion (GCONV=1E-8) satisfied.	0,4373
	>= 2 - < 5 cm	1009	55,7	85	8,4	924	91,6	NE	NE	NE	NE	NE	NE	991	54,4	98	9,9	893	90,1	NE	NE	NE	NE	NE	NE	0,2953	0,86	0,64	1,15		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	22	15,8	117	84,2	NE	NE	NE	NE	NE	NE	165	9,1	34	20,6	131	79,4	76,6	64,4	NE	NE	NE	NE	0,3742	0,78	0,46	1,34		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	108	8,0	1239	92,0	NE	NE	NE	NE	NE	NE	1350	74,1	142	10,5	1208	89,5	NE	NE	NE	NE	NE	NE	0,0269	0,75	0,59	0,97		Convergence criterion (GCONV=1E-8) satisfied.	0,9547
	No	464	25,6	28	6,0	436	94,0	NE	NE	NE	NE	NE	NE	473	25,9	38	8,0	435	92,0	NE	NE	NE	NE	NE	NE	0,2838	0,77	0,47	1,25		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	92	7,3	1160	92,7	NE	NE	NE	NE	NE	NE	1255	68,8	124	9,9	1131	90,1	NE	NE	NE	NE	NE	NE	0,0313	0,74	0,57	0,97		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	2	8,0	23	92,0	NE	NE	NE	NE	NE	NE	31	1,7	1	3,2	30	96,8	NE	NE	NE	NE	NE	NE	0,4213	2,58	0,23	28,49		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	39	8,2	438	91,8	NE	NE	NE	NE	NE	NE	484	26,5	47	9,7	437	90,3	NE	NE	NE	NE	NE	NE	0,4051	0,84	0,55	1,28		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	3	5,8	49	94,2	NE	NE	NE	NE	NE	NE	51	2,8	8	15,7	43	84,3	NE	56,8	NE	NE	NE	NE	0,1052	0,35	0,09	1,32		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

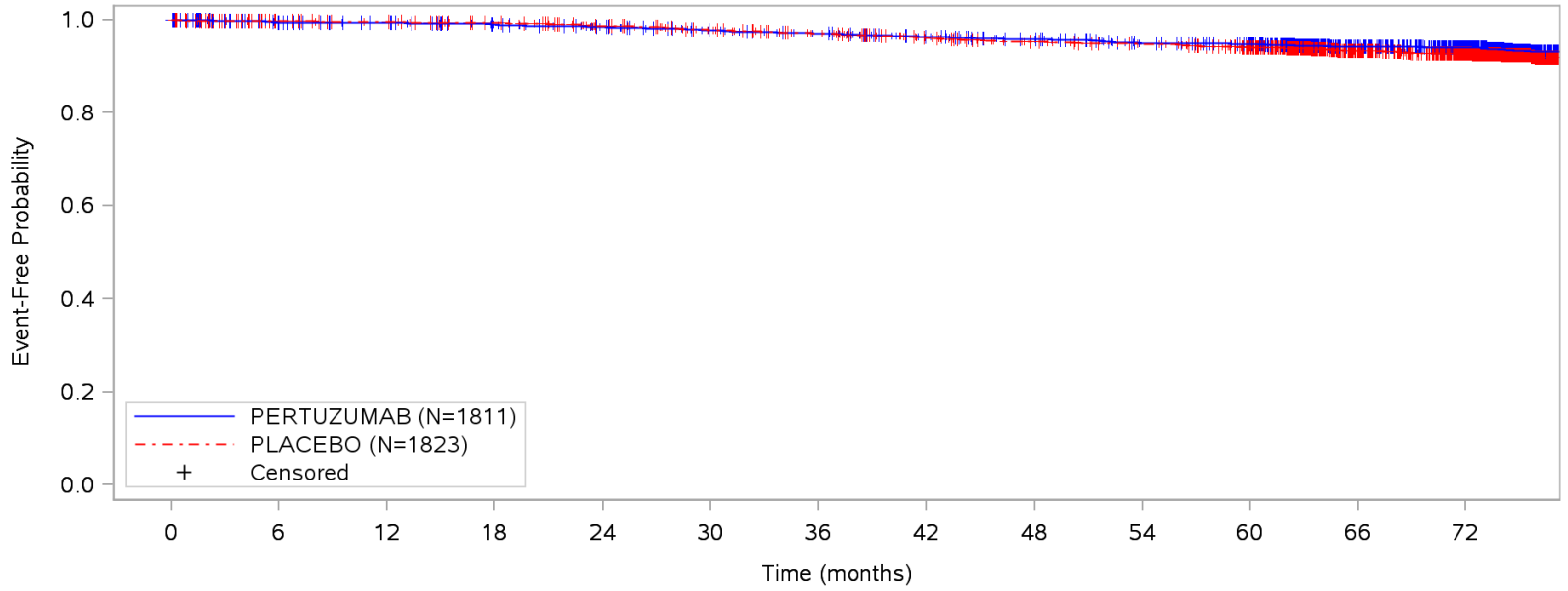
Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_tte_26c_19JUN2019_CHON_DRFI_SG.xls
10AUG2020 14:54

Wirksamkeit (Datenschnitt: 19.06.2019)

Time-to-Event (TTE) Analysen

KM Plots

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Overall survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

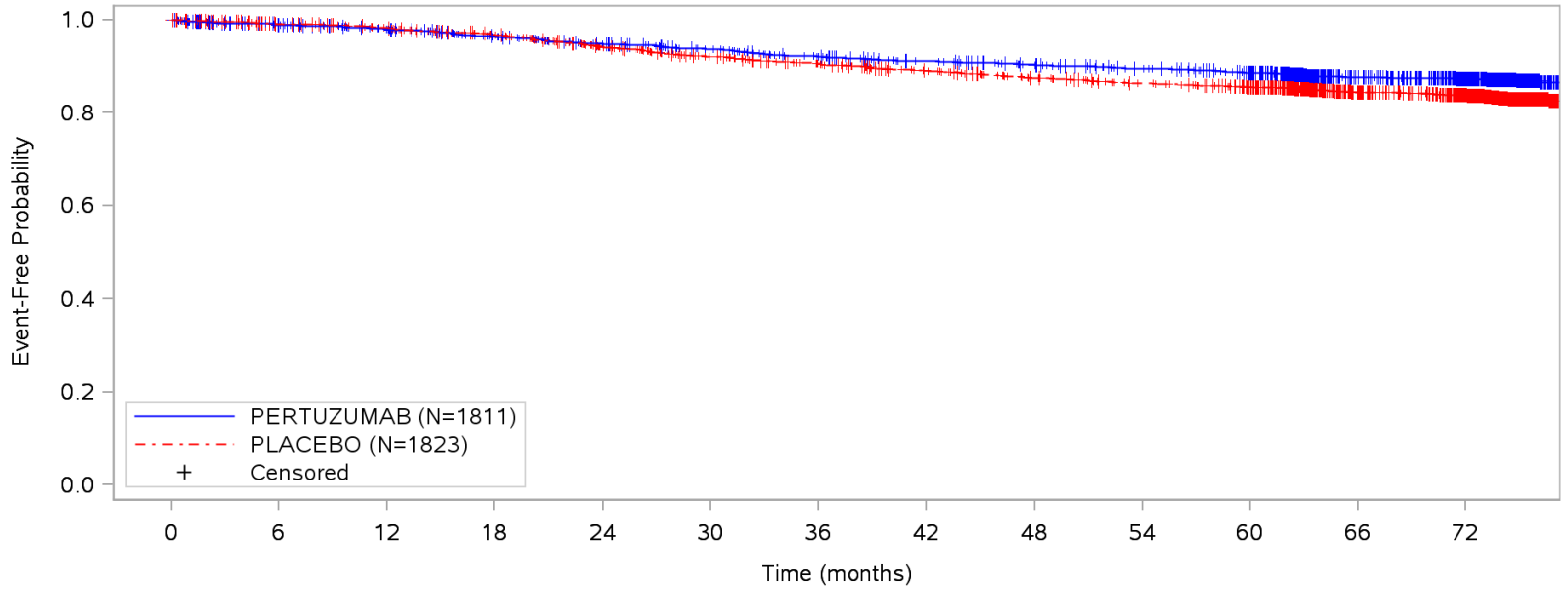


Patients at risk													
PERTUZUMAB	1811	1753	1739	1720	1704	1682	1668	1645	1622	1592	1567	1283	1092
PLACEBO	1823	1780	1771	1753	1730	1707	1684	1649	1625	1611	1576	1241	1066
Patients censored													
PERTUZUMAB	0	48	61	74	80	91	94	104	118	132	153	430	617
PLACEBO	0	39	46	59	70	79	89	106	115	122	143	468	635

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/g_eff_tte_km_26c_19JUN2019_CHON_OS.pdf
30MAR2020 11:32

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)

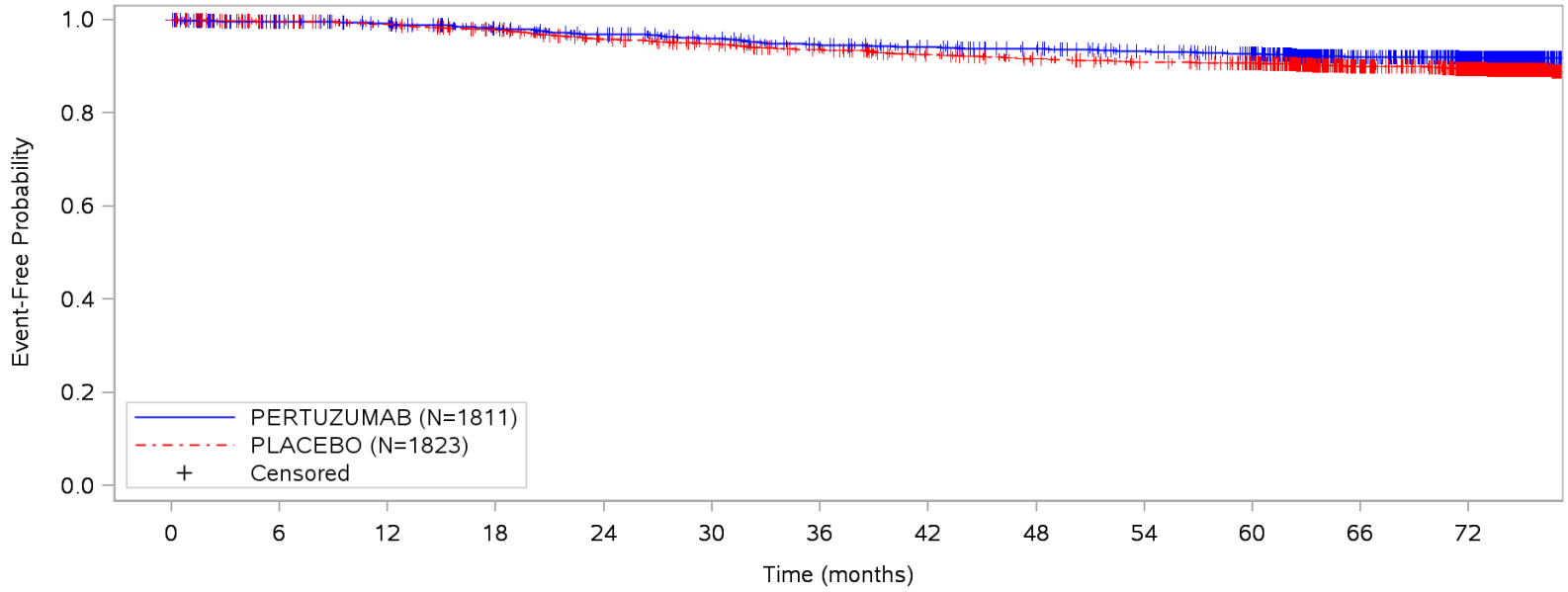


Patients at risk													
PERTUZUMAB	1811	1743	1714	1674	1641	1609	1578	1548	1525	1500	1467	1190	1037
PLACEBO	1823	1766	1742	1705	1649	1605	1568	1527	1495	1467	1434	1116	976
Patients censored													
PERTUZUMAB	0	50	63	74	79	92	95	108	119	131	148	412	560
PLACEBO	0	42	51	62	70	78	88	104	111	119	138	440	572

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/g_eff_tte_km_26c_19JUN2019_CHON_DFS.pdf
30MAR2020 11:34

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)



Patients at risk													
PERTUZUMAB	1811	1749	1727	1694	1667	1638	1607	1586	1565	1541	1510	1230	1063
PLACEBO	1823	1774	1757	1725	1678	1649	1615	1575	1551	1530	1504	1178	1024
Patients censored													
PERTUZUMAB	0	57	71	85	92	104	112	124	140	155	176	447	612
PLACEBO	0	42	50	61	72	84	97	117	126	135	157	474	622

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/g_eff_tte_km_26c_19JUN2019_CHON_DRFI.pdf
30MAR2020 11:37

Wirksamkeit (Datenschnitt: 19.06.2019)

Responder Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Recurrence/death rate
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Dichotomous analysis (efficacy)

		PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1811	100,0	219	12,1	1823	100,0	287	15,7	0,73		Algorithm converged.	0,60	0,88	-0,033		Algorithm converged.	-0,055	-0,012		0,77		Algorithm converged.	0,65	0,90	0,0014	1,30		Algorithm converged.	1,11	1,53

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_resp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_resp_26c_19JUN2019_CHON_RESP1_ST.xls
11AUG2020 14:29

Wirksamkeit (Datenschnitt: 19.06.2019)

Landmark Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event landmark analysis

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients included in analysis	1811 (100%)		1823 (100%)
Patients with event (%)	108 (6.0%)		130 (7.1%)
Earliest contributing event			
DEATH	108		130
Patients without event (%)	1703 (94.0%)		1693 (92.9%)
Time to event (months)			
Median	NE		NE
95% CI	NE		NE
25% and 75%-ile	NE		NE
Range	0.0* - 89.0*		0.0* - 88.5*
Time point analysis			
0.5 year			
Patients remaining at risk	1753		1780
Event free proportion (%)	99,44		99,78
95% CI	(99.09, 99.78)		(99.56, 100.00)
1 year			
Patients remaining at risk	1739		1771
Event free proportion (%)	99,38		99,67
95% CI	(99.01, 99.74)		(99.40, 99.93)
1.5 years			
Patients remaining at risk	1720		1753
Event free proportion (%)	99,03		99,38
95% CI	(98.58, 99.49)		(99.02, 99.75)

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
2 years			
Patients remaining at risk	1704		1730
Event free proportion (%)	98,46		98,7
95% CI	(97.88, 99.03)		(98.17, 99.23)
2.5 years			
Patients remaining at risk	1682		1707
Event free proportion (%)	97,82		97,9
95% CI	(97.13, 98.50)		(97.23, 98.57)
3 years			
Patients remaining at risk	1668		1684
Event free proportion (%)	97,18		97,15
95% CI	(96.40, 97.96)		(96.37, 97.93)
3.5 years			
Patients remaining at risk	1645		1649
Event free proportion (%)	96,42		96,11
95% CI	(95.54, 97.29)		(95.20, 97.01)
4 years			
Patients remaining at risk	1622		1625
Event free proportion (%)	95,83		95,23
95% CI	(94.89, 96.77)		(94.23, 96.23)
4.5 years			
Patients remaining at risk	1592		1611
Event free proportion (%)	94,94		94,82
95% CI	(93.90, 95.97)		(93.78, 95.86)
5 years			

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients remaining at risk	1567		1576
Event free proportion (%)	94,7		93,99
95% CI	(93.64, 95.76)		(92.87, 95.11)
5.5 years			
Patients remaining at risk	1283		1241
Event free proportion (%)	94,24		93,3
95% CI	(93.13, 95.35)		(92.10, 94.49)
6 years			
Patients remaining at risk	1092		1066
Event free proportion (%)	93,93		92,68
95% CI	(92.78, 95.07)		(91.42, 93.94)
Stratified analysis			
p-value (log-rank)		0,136	
Hazard ratio		0,82	
95% CI		(0.64, 1.06)	
Unstratified analysis			
p-value (log-rank)		0,1661	
Hazard ratio		0,84	
95% CI		(0.65, 1.08)	

* Censored observation.
Summaries of time to event (median, percentiles) are based on Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Hazard ratios were estimated by Cox regression.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_lma.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/eff_lma_26c_19JUN2019_CHON_OS_ST.xls
30MAR2020 16:16

Wirksamkeit (Datenschnitt: 10.01.2022)

Time-to-Event (TTE) Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	140	7,7	1671	92,3	NE	NE	NE	NE	NE	NE	1823	100,0	175	9,6	1648	90,4	NE	NE	NE	NE	NE	NE	0,0460	0,798	0,638	0,996		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_OS_ST.xls
04MAY2022 9:11

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	256	14,1	1555	85,9	NE	NE	NE	NE	NE	NE	1823	100,0	347	19,0	1476	81,0	NE	112,8	NE	NE	NE	NE	<.0001	0,724	0,615	0,851		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DFS_ST.xls
04MAY2022 9:15

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival - Time to recurrence
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	231	12,8	1580	87,2	NE	NE	NE	NE	NE	NE	1823	100,0	319	17,5	1504	82,5	NE	112,8	NE	NE	NE	NE	<.0001	0,709	0,598	0,840		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DFSREC_ST.xls
04MAY2022 13:13

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival - Time to death
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	25	1,4	1786	98,6	NE	NE	NE	NE	NE	NE	1823	100,0	28	1,5	1795	98,5	NE	NE	NE	NE	NE	NE	0,6826	0,893	0,520	1,535		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DFSDTH_ST.xls
04MAY2022 13:07

POPULATION: HR negative or node positive ITT
ENDPOINT: Invasive disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	224	12,4	1587	87,6	NE	NE	NE	NE	NE	NE	1823	100,0	300	16,5	1523	83,5	NE	112,8	NE	NE	NE	NE	0,0005	0,734	0,617	0,874		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_IDFS_ST.xls
04MAY2022 12:07

POPULATION: HR negative or node positive ITT
ENDPOINT: Invasive disease-free survival including second primary non-breast cancer
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	252	13,9	1559	86,1	NE	NE	NE	NE	NE	NE	1823	100,0	335	18,4	1488	81,6	NE	112,8	NE	NE	NE	NE	0,0003	0,739	0,627	0,870		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_IDFSS_ST.xls
04MAY2022 12:29

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	1811	100,0	146	8,1	1665	91,9	NE	NE	NE	NE	NE	NE	1823	100,0	201	11,0	1622	89,0	NE	NE	NE	NE	NE	NE	0,0026	0,722	0,583	0,893		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DRFI_ST.xls
04MAY2022 9:20

Wirksamkeit (Datenschnitt: 10.01.2022)

Time-to-Event (TTE) Analysen

Subgruppen

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	140	7,7	1671	92,3	NE	NE	NE	NE	NE	NE	1823	100,0	175	9,6	1648	90,4	NE	NE	NE	NE	NE	NE	0,0523	0,803	0,643	1,003		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	2	3,9	49	96,1	NE	NE	NE	NE	NE	NE	43	2,4	3	7,0	40	93,0	NE	NE	NE	NE	NE	NE	0,5146	0,556	0,093	3,330		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	8	3,1	249	96,9	NE	NE	NE	NE	NE	NE	278	15,2	9	3,2	269	96,8	NE	NE	NE	NE	NE	NE	0,9104	0,947	0,365	2,454		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	51	5,6	856	94,4	NE	NE	NE	NE	NE	NE	900	49,4	67	7,4	833	92,6	NE	NE	NE	NE	NE	NE	0,1345	0,758	0,527	1,091		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	79	13,3	517	86,7	NE	NE	NE	NE	NE	NE	602	33,0	96	15,9	506	84,1	NE	NE	NE	NE	NE	NE	0,2083	0,826	0,613	1,113		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	113	7,9	1326	92,1	NE	NE	NE	NE	NE	NE	1448	79,4	141	9,7	1307	90,3	NE	NE	NE	NE	NE	NE	0,0787	0,801	0,626	1,026		Convergence criterion (GCONV=1E-8) satisfied.	0,9824
	Non-anthracycline	372	20,5	27	7,3	345	92,7	NE	NE	NE	NE	NE	NE	375	20,6	34	9,1	341	90,9	NE	113,5	NE	NE	NE	NE	0,3947	0,803	0,485	1,332		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	78	9,0	786	91,0	NE	NE	NE	NE	NE	NE	858	47,1	84	9,8	774	90,2	NE	NE	NE	NE	NE	NE	0,5806	0,917	0,674	1,248		Convergence criterion (GCONV=1E-8) satisfied.	0,2205
	Positive (ER and/or PgR positive)	947	52,3	62	6,5	885	93,5	NE	NE	NE	NE	NE	NE	965	52,9	91	9,4	874	90,6	NE	NE	NE	NE	NE	NE	0,0244	0,692	0,501	0,955		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	17	6,4	248	93,6	NE	NE	NE	NE	NE	NE	260	14,3	18	6,9	242	93,1	NE	NE	NE	NE	NE	NE	0,7851	0,912	0,470	1,770		Convergence criterion (GCONV=1E-8) satisfied.	0,4637
	Western Europe	827	45,7	61	7,4	766	92,6	NE	NE	NE	NE	NE	NE	822	45,1	76	9,2	746	90,8	NE	NE	NE	NE	NE	NE	0,2027	0,804	0,574	1,126		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	40	8,2	450	91,8	NE	NE	NE	NE	NE	NE	512	28,1	44	8,6	468	91,4	NE	NE	NE	NE	NE	NE	0,7813	0,941	0,613	1,444		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	47	2,6	8	17,0	39	83,0	NE	89,1	NE	NE	NE	NE	0,0636	0,257	0,055	1,210		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	20	10,8	166	89,2	NE	NE	NE	NE	NE	NE	182	10,0	29	15,9	153	84,1	NE	NE	NE	NE	NE	NE	0,1575	0,665	0,376	1,175		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	95	7,7	1145	92,3	NE	NE	NE	NE	NE	NE	1246	68,3	116	9,3	1130	90,7	NE	NE	NE	NE	NE	NE	0,1499	0,820	0,625	1,075		Convergence criterion (GCONV=1E-8) satisfied.	0,7990
	Protocol amendment B	571	31,5	45	7,9	526	92,1	NE	NE	NE	NE	NE	NE	577	31,7	59	10,2	518	89,8	NE	NE	NE	NE	NE	NE	0,1888	0,772	0,523	1,137		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	10	3,2	298	96,8	NE	NE	NE	NE	NE	NE	321	17,6	12	3,7	309	96,3	NE	NE	NE	NE	NE	NE	0,7165	0,857	0,370	1,983		Convergence criterion (GCONV=1E-8) satisfied.	0,8671
	>= 1 positive nodes	1503	83,0	130	8,6	1373	91,4	NE	NE	NE	NE	NE	NE	1502	82,4	163	10,9	1339	89,1	NE	NE	NE	NE	NE	NE	0,0518	0,796	0,632	1,002		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	54	6,2	819	93,8	NE	NE	NE	NE	NE	NE	885	48,5	62	7,0	823	93,0	NE	113,5	NE	NE	NE	NE	0,5051	0,884	0,613	1,273		Convergence criterion (GCONV=1E-8) satisfied.	0,5139
	Postmenopausal	933	51,5	86	9,2	847	90,8	NE	NE	NE	NE	NE	NE	929	51,0	112	12,1	817	87,9	NE	NE	NE	NE	NE	NE	0,0543	0,760	0,573	1,006		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	1	11,1	8	88,9	NE	56,2	NE	NE	NE	NE	0,4292	<0.001	0,000	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	111	7,0	1470	93,0	NE	NE	NE	NE	NE	NE	1604	88,0	139	8,7	1465	91,3	NE	NE	NE	NE	NE	NE	0,0798	0,800	0,624	1,027		Convergence criterion (GCONV=1E-8) satisfied.	0,9528
	>= 65	230	12,7	29	12,6	201	87,4	NE	NE	NE	NE	NE	NE	219	12,0	36	16,4	183	83,6	NE	109,4	NE	NE	NE	NE	0,4091	0,814	0,499	1,328		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	0	0,0	32	100,0	NE	NE	NE	NE	NE	NE	24	1,3	4	16,7	20	83,3	NE	60,0	NE	NE	109,5	NE	0,0290	<0.001	0,000	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	39	7,1	513	92,9	NE	NE	NE	NE	NE	NE	557	30,6	44	7,9	513	92,1	NE	NE	NE	NE	NE	NE	0,5933	0,889	0,578	1,369		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	95	8,2	1066	91,8	NE	NE	NE	NE	NE	NE	1173	64,3	120	10,2	1053	89,8	NE	NE	NE	NE	NE	NE	0,1002	0,798	0,610	1,045		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	6	9,1	60	90,9	NE	NE	NE	NE	NE	NE	69	3,8	7	10,1	62	89,9	NE	107,9	NE	NE	NE	NE	0,7943	0,865	0,291	2,576		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	36	4,9	692	95,1	NE	NE	NE	NE	NE	NE	715	39,2	49	6,9	666	93,1	NE	NE	NE	NE	NE	NE	0,1149	0,709	0,461	1,090		Convergence criterion (GCONV=1E-8) satisfied.	0,4692

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	104	9,6	979	90,4	NE	NE	NE	NE	NE	NE	1107	60,7	126	11,4	981	88,6	NE	113,5	NE	NE	NE	NE	0,2273	0,853	0,658	1,106		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	32	4,8	628	95,2	NE	NE	NE	NE	NE	NE	665	36,5	49	7,4	616	92,6	NE	NE	NE	NE	NE	NE	0,0577	0,652	0,417	1,017		Convergence criterion (GCONV=1E-8) satisfied.	0,4595
	>= 2 - < 5 cm	1009	55,7	84	8,3	925	91,7	NE	NE	NE	NE	NE	NE	991	54,4	97	9,8	894	90,2	NE	NE	NE	NE	NE	NE	0,2777	0,851	0,635	1,140		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	24	17,3	115	82,7	NE	107,1	NE	NE	NE	NE	165	9,1	29	17,6	136	82,4	113,5	113,5	NE	NE	113,5	NE	0,9714	0,990	0,576	1,701		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	96	7,1	1251	92,9	NE	NE	NE	NE	NE	NE	1350	74,1	129	9,6	1221	90,4	NE	NE	NE	NE	NE	NE	0,0239	0,738	0,567	0,962		Convergence criterion (GCONV=1E-8) satisfied.	0,2376
	No	464	25,6	44	9,5	420	90,5	NE	NE	NE	NE	NE	NE	473	25,9	46	9,7	427	90,3	NE	NE	NE	NE	NE	NE	0,9788	0,994	0,658	1,503		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	97	7,7	1155	92,3	NE	NE	NE	NE	NE	NE	1255	68,8	122	9,7	1133	90,3	NE	NE	NE	NE	NE	NE	0,0938	0,797	0,610	1,040		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	2	8,0	23	92,0	NE	NE	NE	NE	NE	NE	31	1,7	2	6,5	29	93,5	NE	NE	NE	NE	NE	NE	0,8248	1,248	0,175	8,876		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	38	8,0	439	92,0	NE	NE	NE	NE	NE	NE	484	26,5	42	8,7	442	91,3	NE	NE	NE	NE	NE	NE	0,6747	0,910	0,587	1,412		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	3	5,8	49	94,2	NE	NE	NE	NE	NE	NE	51	2,8	9	17,6	42	82,4	NE	89,1	NE	NE	NE	NE	0,0688	0,317	0,086	1,171		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_OS_SG.xls
04MAY2022 9:13

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	256	14,1	1555	85,9	NE	NE	NE	NE	NE	NE	1823	100,0	347	19,0	1476	81,0	NE	112,8	NE	NE	NE	NE	0,0001	0,729	0,620	0,857		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	7	13,7	44	86,3	NE	110,1	NE	NE	NE	NE	43	2,4	6	14,0	37	86,0	NE	85,4	NE	NE	NE	NE	0,8432	0,895	0,300	2,676		Convergence criterion (GCONV=1E-8) satisfied.	0,7767
	0 positive nodes, tumor > 1 cm	257	14,2	23	8,9	234	91,1	NE	NE	NE	NE	NE	NE	278	15,2	30	10,8	248	89,2	NE	112,8	NE	NE	NE	NE	0,4815	0,823	0,478	1,417		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	102	11,2	805	88,8	NE	NE	NE	NE	NE	NE	900	49,4	151	16,8	749	83,2	NE	NE	NE	NE	NE	NE	0,0011	0,660	0,514	0,849		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	124	20,8	472	79,2	NE	104,2	NE	NE	NE	NE	602	33,0	160	26,6	442	73,4	76,6	54,6	105,7	NE	NE	NE	0,0245	0,765	0,605	0,967		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	207	14,4	1232	85,6	NE	NE	NE	NE	NE	NE	1448	79,4	280	19,3	1168	80,7	NE	NE	NE	NE	NE	NE	0,0005	0,727	0,607	0,870		Convergence criterion (GCONV=1E-8) satisfied.	0,9529
	Non-anthracycline	372	20,5	49	13,2	323	86,8	NE	NE	NE	NE	NE	NE	375	20,6	67	17,9	308	82,1	112,8	112,8	NE	NE	112,8	NE	0,0984	0,734	0,507	1,061		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	126	14,6	738	85,4	NE	NE	NE	NE	NE	NE	858	47,1	147	17,1	711	82,9	NE	112,8	NE	NE	NE	NE	0,1375	0,835	0,659	1,060		Convergence criterion (GCONV=1E-8) satisfied.	0,1353
	Positive (ER and/or PgR positive)	947	52,3	130	13,7	817	86,3	NE	NE	NE	NE	NE	NE	965	52,9	200	20,7	765	79,3	NE	102,7	NE	NE	NE	NE	0,0001	0,650	0,522	0,811		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	30	11,3	235	88,7	NE	NE	NE	NE	NE	NE	260	14,3	38	14,6	222	85,4	NE	NE	NE	NE	NE	NE	0,2409	0,752	0,466	1,213		Convergence criterion (GCONV=1E-8) satisfied.	0,4316
	Western Europe	827	45,7	120	14,5	707	85,5	NE	NE	NE	NE	NE	NE	822	45,1	160	19,5	662	80,5	NE	110,1	NE	NE	NE	NE	0,0117	0,738	0,583	0,936		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	75	15,3	415	84,7	NE	NE	NE	NE	NE	NE	512	28,1	95	18,6	417	81,4	112,8	112,8	NE	NE	112,8	NE	0,1606	0,805	0,595	1,090		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	4	9,3	39	90,7	NE	NE	NE	NE	NE	NE	47	2,6	14	29,8	33	70,2	56,8	35,0	NE	NE	NE	NE	0,0211	0,293	0,096	0,889		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	27	14,5	159	85,5	NE	NE	NE	NE	NE	NE	182	10,0	40	22,0	142	78,0	NE	72,1	NE	NE	NE	NE	0,0756	0,645	0,396	1,050		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	168	13,5	1072	86,5	NE	NE	NE	NE	NE	NE	1246	68,3	224	18,0	1022	82,0	NE	112,8	NE	NE	NE	NE	0,0028	0,738	0,604	0,902		Convergence criterion (GCONV=1E-8) satisfied.	0,8469
	Protocol amendment B	571	31,5	88	15,4	483	84,6	105,9	105,9	NE	105,9	105,9	NE	577	31,7	123	21,3	454	78,7	102,7	92,7	NE	NE	NE	NE	0,0154	0,714	0,543	0,939		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	30	9,7	278	90,3	NE	NE	NE	NE	NE	NE	321	17,6	36	11,2	285	88,8	NE	112,8	NE	NE	NE	NE	0,5267	0,856	0,527	1,389		Convergence criterion (GCONV=1E-8) satisfied.	0,4971
	>= 1 positive nodes	1503	83,0	226	15,0	1277	85,0	NE	NE	NE	NE	NE	NE	1502	82,4	311	20,7	1191	79,3	NE	110,1	NE	NE	NE	NE	0,0001	0,714	0,601	0,847		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	121	13,9	752	86,1	NE	NE	NE	NE	NE	NE	885	48,5	161	18,2	724	81,8	112,8	112,8	NE	NE	NE	NE	0,0162	0,749	0,592	0,949		Convergence criterion (GCONV=1E-8) satisfied.	0,8696
	Postmenopausal	933	51,5	135	14,5	798	85,5	NE	NE	NE	NE	NE	NE	929	51,0	181	19,5	748	80,5	NE	NE	NE	NE	NE	NE	0,0052	0,728	0,583	0,910		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	5	55,6	4	44,4	50,0	25,8	86,9	80,3	49,1	NE	0,0367	<0.001	0,000	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	214	13,5	1367	86,5	NE	NE	NE	NE	NE	NE	1604	88,0	290	18,1	1314	81,9	NE	112,8	NE	NE	NE	NE	0,0005	0,731	0,612	0,872		Convergence criterion (GCONV=1E-8) satisfied.	0,9540
	>= 65	230	12,7	42	18,3	188	81,7	NE	96,1	NE	NE	NE	NE	219	12,0	57	26,0	162	74,0	95,9	61,8	NE	NE	NE	NE	0,1069	0,721	0,484	1,075		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	2	6,3	30	93,8	NE	NE	NE	NE	NE	NE	24	1,3	8	33,3	16	66,7	73,4	44,2	NE	NE	99,2	NE	0,0135	0,177	0,038	0,835		Convergence criterion (GCONV=1E-8) satisfied.	0,0815
	Grade 2	552	30,5	67	12,1	485	87,9	NE	NE	NE	NE	NE	NE	557	30,6	105	18,9	452	81,1	112,8	110,1	NE	NE	NE	NE	0,0022	0,622	0,458	0,845		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	173	14,9	988	85,1	NE	NE	NE	NE	NE	NE	1173	64,3	224	19,1	949	80,9	NE	NE	NE	NE	NE	NE	0,0096	0,770	0,631	0,939		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	14	21,2	52	78,8	NE	57,3	NE	NE	NE	NE	69	3,8	10	14,5	59	85,5	NE	NE	NE	NE	NE	NE	0,3101	1,518	0,674	3,418		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	77	10,6	651	89,4	NE	NE	NE	NE	NE	NE	715	39,2	122	17,1	593	82,9	112,8	112,8	NE	NE	NE	NE	0,0003	0,592	0,445	0,787		Convergence criterion (GCONV=1E-8) satisfied.	0,0763

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	179	16,5	904	83,5	NE	NE	NE	NE	NE	NE	1107	60,7	225	20,3	882	79,7	NE	107,0	NE	NE	NE	NE	0,0382	0,813	0,668	0,989		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	74	11,2	586	88,8	NE	NE	NE	NE	NE	NE	665	36,5	109	16,4	556	83,6	NE	NE	NE	NE	NE	NE	0,0074	0,670	0,498	0,900		Convergence criterion (GCONV=1E-8) satisfied.	0,7616
	>= 2 - < 5 cm	1009	55,7	149	14,8	860	85,2	NE	NE	NE	NE	NE	NE	991	54,4	187	18,9	804	81,1	112,8	112,8	NE	NE	NE	NE	0,0171	0,770	0,621	0,955		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	33	23,7	106	76,3	105,9	62,5	NE	NE	NE	NE	165	9,1	51	30,9	114	69,1	51,0	41,9	99,1	NE	NE	NE	0,2021	0,753	0,486	1,166		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	186	13,8	1161	86,2	NE	NE	NE	NE	NE	NE	1350	74,1	268	19,9	1082	80,1	112,8	112,8	NE	NE	NE	NE	<.0001	0,675	0,560	0,814		Convergence criterion (GCONV=1E-8) satisfied.	0,1116
	No	464	25,6	70	15,1	394	84,9	NE	NE	NE	NE	NE	NE	473	25,9	79	16,7	394	83,3	NE	NE	NE	NE	NE	NE	0,6037	0,918	0,666	1,267		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	176	14,1	1076	85,9	NE	NE	NE	NE	NE	NE	1255	68,8	237	18,9	1018	81,1	NE	NE	NE	NE	NE	NE	0,0018	0,734	0,604	0,892		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	2	8,0	23	92,0	NE	NE	NE	NE	NE	NE	31	1,7	5	16,1	26	83,9	NE	62,7	NE	NE	NE	NE	0,3916	0,495	0,096	2,555		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	73	15,3	404	84,7	NE	NE	NE	NE	NE	NE	484	26,5	88	18,2	396	81,8	112,8	110,6	NE	NE	112,8	NE	0,2303	0,827	0,607	1,128		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	4	7,7	48	92,3	NE	NE	NE	NE	NE	NE	51	2,8	16	31,4	35	68,6	53,7	35,0	NE	NE	NE	NE	0,0035	0,225	0,075	0,674		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	1	20,0	4	80,0	NE	47,2	NE	NE	47,2	NE	2	0,1	1	50,0	1	50,0	42,1	42,1	NE	NE	42,1	NE	0,3497	0,283	0,017	4,715		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DFS_SG.xls
04MAY2022 9:17

POPULATION: HR negative or node positive ITT
ENDPOINT: Distant recurrence-free interval
MODEL: Unstratified analysis
STUDY: BO25126
Time to event analysis (efficacy)

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	1811	100,0	146	8,1	1665	91,9	NE	NE	NE	NE	NE	NE	1823	100,0	201	11,0	1622	89,0	NE	NE	NE	NE	NE	NE	0,0034	0,728	0,588	0,901		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,8	0	0,0	51	100,0	NE	NE	NE	NE	NE	NE	43	2,4	2	4,7	41	95,3	NE	NE	NE	NE	NE	NE	0,1229	<0.001	0,000	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	0 positive nodes, tumor > 1 cm	257	14,2	6	2,3	251	97,7	NE	NE	NE	NE	NE	NE	278	15,2	3	1,1	275	98,9	NE	NE	NE	NE	NE	NE	0,2771	2,119	0,530	8,471		Convergence criterion (GCONV=1E-8) satisfied.	
	1-3 positive nodes	907	50,1	51	5,6	856	94,4	NE	NE	NE	NE	NE	NE	900	49,4	68	7,6	832	92,4	NE	NE	NE	NE	NE	NE	0,1131	0,746	0,519	1,073		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 4 positive nodes	596	32,9	89	14,9	507	85,1	NE	NE	NE	NE	NE	NE	602	33,0	128	21,3	474	78,7	NE	93,6	NE	NE	NE	NE	0,0078	0,694	0,529	0,909		Convergence criterion (GCONV=1E-8) satisfied.	
Adjuvant chemotherapy regimen	Anthracycline	1439	79,5	124	8,6	1315	91,4	NE	NE	NE	NE	NE	NE	1448	79,4	159	11,0	1289	89,0	NE	NE	NE	NE	NE	NE	0,0387	0,781	0,618	0,988		Convergence criterion (GCONV=1E-8) satisfied.	0,1683
	Non-anthracycline	372	20,5	22	5,9	350	94,1	NE	NE	NE	NE	NE	NE	375	20,6	42	11,2	333	88,8	NE	NE	NE	NE	NE	NE	0,0132	0,527	0,314	0,882		Convergence criterion (GCONV=1E-8) satisfied.	
Centrally assessed hormone receptor status	Negative (ER and PgR negative)	864	47,7	60	6,9	804	93,1	NE	NE	NE	NE	NE	NE	858	47,1	77	9,0	781	91,0	NE	NE	NE	NE	NE	NE	0,1117	0,761	0,543	1,067		Convergence criterion (GCONV=1E-8) satisfied.	0,7725
	Positive (ER and/or PgR positive)	947	52,3	86	9,1	861	90,9	NE	NE	NE	NE	NE	NE	965	52,9	124	12,8	841	87,2	NE	NE	NE	NE	NE	NE	0,0141	0,710	0,539	0,935		Convergence criterion (GCONV=1E-8) satisfied.	
Geographical region II	USA/Canada	265	14,6	12	4,5	253	95,5	NE	NE	NE	NE	NE	NE	260	14,3	23	8,8	237	91,2	NE	NE	NE	NE	NE	NE	0,0529	0,509	0,253	1,022		Convergence criterion (GCONV=1E-8) satisfied.	0,6835
	Western Europe	827	45,7	70	8,5	757	91,5	NE	NE	NE	NE	NE	NE	822	45,1	90	10,9	732	89,1	NE	NE	NE	NE	NE	NE	0,1128	0,777	0,569	1,062		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia Pacific	490	27,1	41	8,4	449	91,6	NE	NE	NE	NE	NE	NE	512	28,1	56	10,9	456	89,1	NE	NE	NE	NE	NE	NE	0,1693	0,755	0,504	1,129		Convergence criterion (GCONV=1E-8) satisfied.	
	Latin America	43	2,4	3	7,0	40	93,0	NE	NE	NE	NE	NE	NE	47	2,6	8	17,0	39	83,0	NE	56,8	NE	NE	NE	NE	0,1549	0,395	0,105	1,488		Convergence criterion (GCONV=1E-8) satisfied.	

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Other	186	10,3	20	10,8	166	89,2	NE	NE	NE	NE	NE	NE	182	10,0	24	13,2	158	86,8	NE	NE	NE	NE	NE	NE	0,4818	0,809	0,447	1,464		Convergence criterion (GCONV=1E-8) satisfied.	
Protocol version	Protocol A	1240	68,5	88	7,1	1152	92,9	NE	NE	NE	NE	NE	NE	1246	68,3	121	9,7	1125	90,3	NE	NE	NE	NE	NE	NE	0,0220	0,726	0,552	0,956		Convergence criterion (GCONV=1E-8) satisfied.	0,9691
	Protocol amendment B	571	31,5	58	10,2	513	89,8	105,9	105,9	NE	105,9	105,9	NE	577	31,7	80	13,9	497	86,1	NE	103,6	NE	NE	NE	NE	0,0730	0,735	0,524	1,030		Convergence criterion (GCONV=1E-8) satisfied.	
Nodal status	0 positive nodes	308	17,0	6	1,9	302	98,1	NE	NE	NE	NE	NE	NE	321	17,6	5	1,6	316	98,4	NE	NE	NE	NE	NE	NE	0,7325	1,229	0,375	4,027		Convergence criterion (GCONV=1E-8) satisfied.	0,3748
	>= 1 positive nodes	1503	83,0	140	9,3	1363	90,7	NE	NE	NE	NE	NE	NE	1502	82,4	196	13,0	1306	87,0	NE	NE	NE	NE	NE	NE	0,0020	0,712	0,573	0,885		Convergence criterion (GCONV=1E-8) satisfied.	
Menopausal status at randomization	Premenopausal	873	48,2	82	9,4	791	90,6	NE	NE	NE	NE	NE	NE	885	48,5	103	11,6	782	88,4	NE	NE	NE	NE	NE	NE	0,1528	0,810	0,606	1,082		Convergence criterion (GCONV=1E-8) satisfied.	0,3132
	Postmenopausal	933	51,5	64	6,9	869	93,1	NE	NE	NE	NE	NE	NE	929	51,0	97	10,4	832	89,6	NE	NE	NE	NE	NE	NE	0,0070	0,650	0,474	0,891		Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown/Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	9	0,5	1	11,1	8	88,9	NE	49,1	NE	NE	NE	NE	0,4292	<0.001	0,000	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age II	< 65	1581	87,3	130	8,2	1451	91,8	NE	NE	NE	NE	NE	NE	1604	88,0	179	11,2	1425	88,8	NE	NE	NE	NE	NE	NE	0,0060	0,729	0,582	0,914		Convergence criterion (GCONV=1E-8) satisfied.	0,9577
	>= 65	230	12,7	16	7,0	214	93,0	NE	NE	NE	NE	NE	NE	219	12,0	22	10,0	197	90,0	NE	NE	NE	NE	NE	NE	0,3077	0,716	0,376	1,364		Convergence criterion (GCONV=1E-8) satisfied.	
Histological grade	Grade 1	32	1,8	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	24	1,3	4	16,7	20	83,3	NE	46,2	NE	NE	NE	NE	0,1031	0,195	0,022	1,745		Convergence criterion (GCONV=1E-8) satisfied.	-
	Grade 2	552	30,5	36	6,5	516	93,5	NE	NE	NE	NE	NE	NE	557	30,6	59	10,6	498	89,4	NE	NE	NE	NE	NE	NE	0,0178	0,609	0,402	0,922		Convergence criterion (GCONV=1E-8) satisfied.	
	Grade 3	1161	64,1	102	8,8	1059	91,2	NE	NE	NE	NE	NE	NE	1173	64,3	135	11,5	1038	88,5	NE	NE	NE	NE	NE	NE	0,0376	0,762	0,589	0,985		Convergence criterion (GCONV=1E-8) satisfied.	
	Unevaluable/Unknown/Missing	66	3,6	7	10,6	59	89,4	NE	NE	NE	NE	NE	NE	69	3,8	3	4,3	66	95,7	NE	NE	NE	NE	NE	NE	0,1849	2,423	0,627	9,371		Convergence criterion (GCONV=1E-8) satisfied.	
Type of surgery for primary tumor	Breast conserving surgery	728	40,2	34	4,7	694	95,3	NE	NE	NE	NE	NE	NE	715	39,2	52	7,3	663	92,7	NE	NE	NE	NE	NE	NE	0,0316	0,625	0,406	0,963		Convergence criterion (GCONV=1E-8) satisfied.	0,3905

		PERTUZUMAB (N=1811)												PLACEBO (N=1823)												PERTUZUMAB vs PLACEBO						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
	Mastectomy	1083	59,8	112	10,3	971	89,7	NE	NE	NE	NE	NE	NE	1107	60,7	149	13,5	958	86,5	NE	NE	NE	NE	NE	NE	0,0434	0,777	0,608	0,993		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	1	<0.1	0	0,0	1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Tumor size	0 - < 2 cm	660	36,4	33	5,0	627	95,0	NE	NE	NE	NE	NE	NE	665	36,5	52	7,8	613	92,2	NE	NE	NE	NE	NE	NE	0,0352	0,628	0,406	0,972		Convergence criterion (GCONV=1E-8) satisfied.	0,7002
	>= 2 - < 5 cm	1009	55,7	90	8,9	919	91,1	NE	NE	NE	NE	NE	NE	991	54,4	114	11,5	877	88,5	NE	NE	NE	NE	NE	NE	0,0739	0,778	0,590	1,025		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 5 cm	139	7,7	23	16,5	116	83,5	NE	105,9	NE	NE	NE	NE	165	9,1	35	21,2	130	78,8	NE	64,4	NE	NE	NE	NE	0,3800	0,790	0,467	1,338		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,2	0	0,0	3	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Loco-regional radiotherapy	Yes	1347	74,4	114	8,5	1233	91,5	NE	NE	NE	NE	NE	NE	1350	74,1	162	12,0	1188	88,0	NE	NE	NE	NE	NE	NE	0,0029	0,697	0,548	0,885		Convergence criterion (GCONV=1E-8) satisfied.	0,4517
	No	464	25,6	32	6,9	432	93,1	NE	NE	NE	NE	NE	NE	473	25,9	39	8,2	434	91,8	NE	NE	NE	NE	NE	NE	0,5057	0,853	0,535	1,362		Convergence criterion (GCONV=1E-8) satisfied.	
Race	White	1252	69,1	99	7,9	1153	92,1	NE	NE	NE	NE	NE	NE	1255	68,8	139	11,1	1116	88,9	NE	NE	NE	NE	NE	NE	0,0097	0,713	0,551	0,922		Convergence criterion (GCONV=1E-8) satisfied.	-
	Black	25	1,4	2	8,0	23	92,0	NE	NE	NE	NE	NE	NE	31	1,7	2	6,5	29	93,5	NE	NE	NE	NE	NE	NE	0,7964	1,293	0,182	9,184		Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	477	26,3	42	8,8	435	91,2	NE	NE	NE	NE	NE	NE	484	26,5	51	10,5	433	89,5	NE	NE	NE	NE	NE	NE	0,3631	0,828	0,550	1,245		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	52	2,9	3	5,8	49	94,2	NE	NE	NE	NE	NE	NE	51	2,8	9	17,6	42	82,4	NE	56,8	NE	NE	NE	NE	0,0665	0,314	0,085	1,161		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,3	0	0,0	5	100,0	NE	NE	NE	NE	NE	NE	2	0,1	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

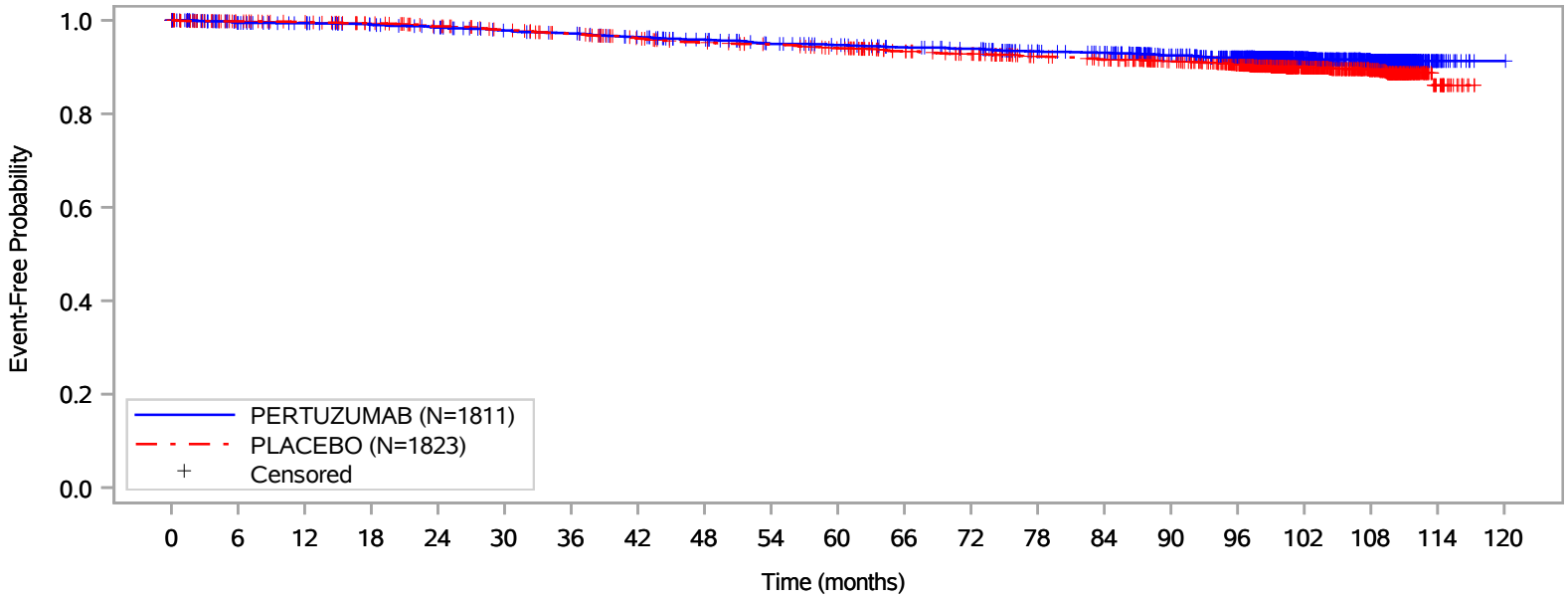
Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_tte.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_tte_26d_10JAN2022_CHON_DRFI_SG.xls
04MAY2022 9:22

Wirksamkeit (Datenschnitt: 10.01.2022)

Time-to-Event (TTE) Analysen

KM Plots

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Overall survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

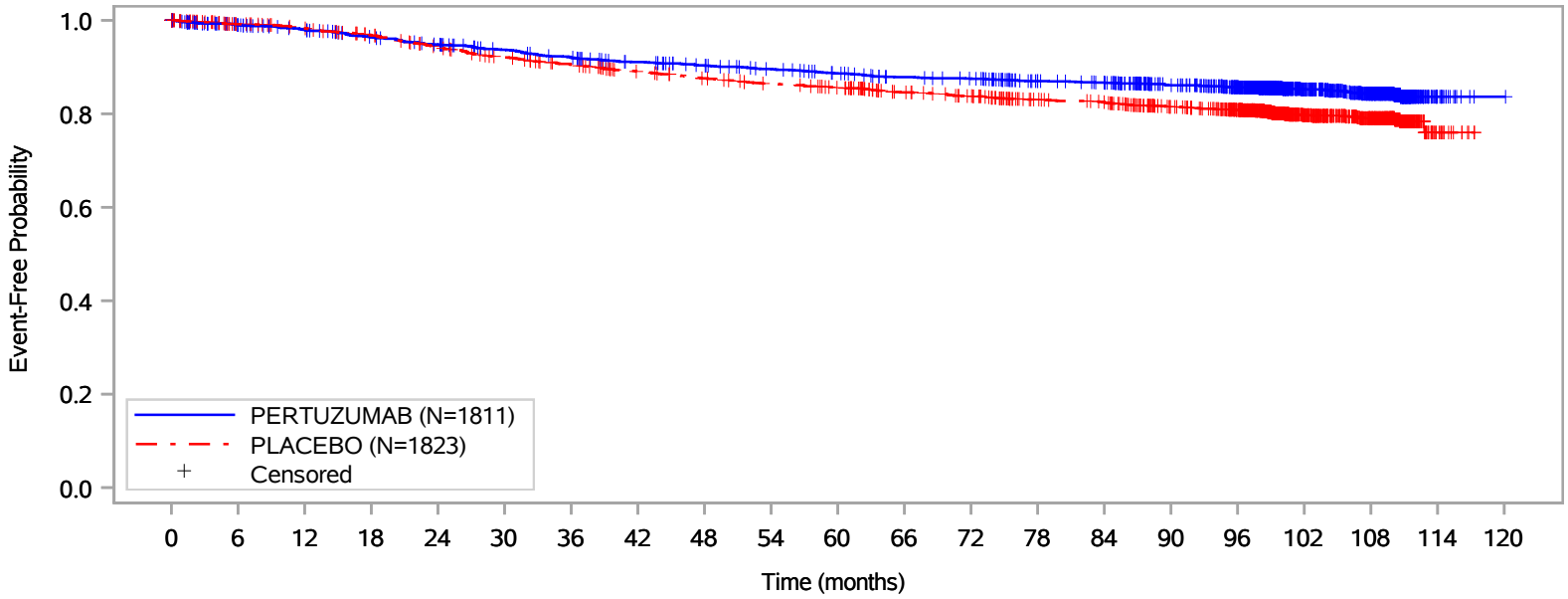


Patients at risk																					
PERTUZUMAB	1811	1753	1739	1720	1704	1682	1668	1645	1622	1595	1582	1564	1552	1517	1503	1437	1358	722	511	23	1
PLACEBO	1823	1782	1771	1752	1729	1707	1684	1650	1629	1616	1594	1556	1536	1499	1481	1435	1356	702	487	27	NE
Patients censored																					
PERTUZUMAB	0	48	61	74	80	91	94	104	118	129	138	148	155	181	190	247	320	953	1160	1648	1670
PLACEBO	0	37	46	60	71	80	89	105	111	117	125	152	163	191	198	238	307	953	1165	1621	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_OS.pdf
04MAY2022 12:45

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

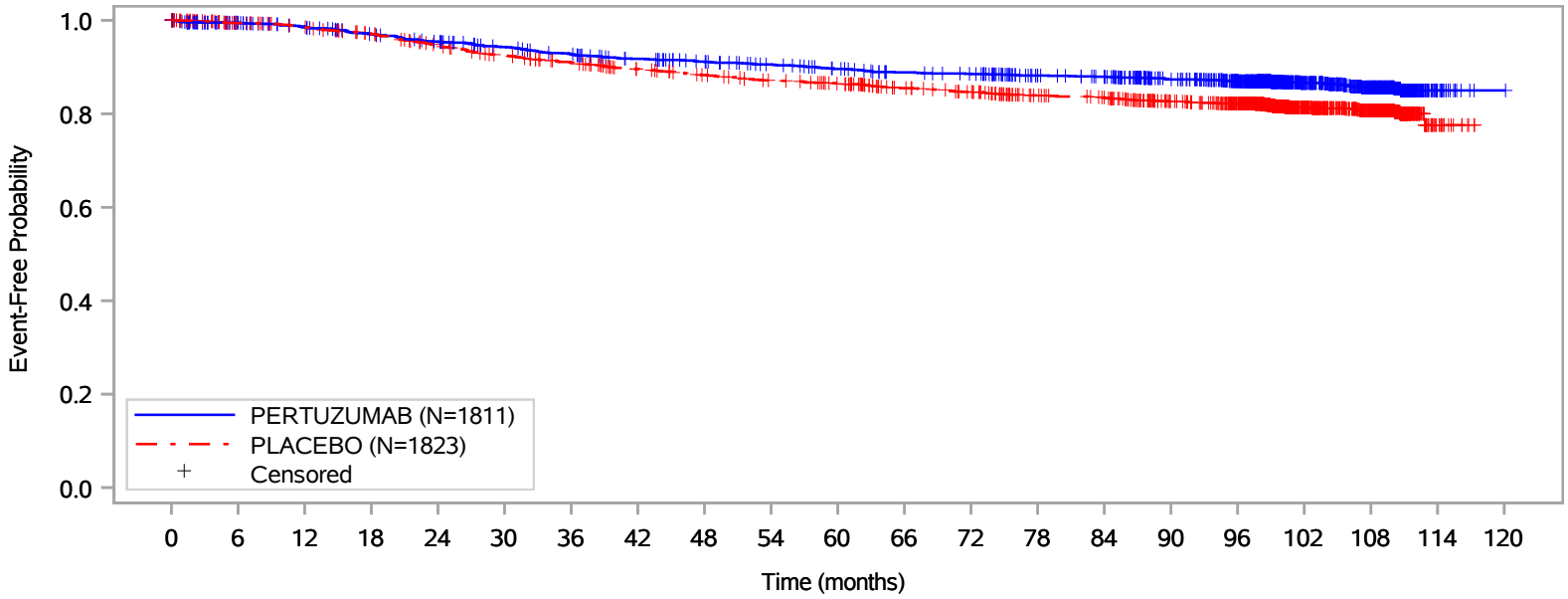


Patients at risk																					
PERTUZUMAB	1811	1743	1714	1674	1641	1609	1578	1548	1525	1502	1477	1453	1443	1400	1387	1315	1236	635	468	18	1
PLACEBO	1823	1766	1742	1704	1648	1604	1568	1528	1498	1471	1449	1401	1378	1331	1314	1254	1175	601	423	15	NE
Patients censored																					
PERTUZUMAB	0	50	63	74	79	92	95	108	119	129	138	149	154	188	196	259	333	928	1089	1537	1554
PLACEBO	0	42	51	63	71	79	88	103	108	115	123	154	164	199	207	251	320	882	1056	1461	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_DFS.pdf
04MAY2022 12:50

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival - Time to recurrence
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

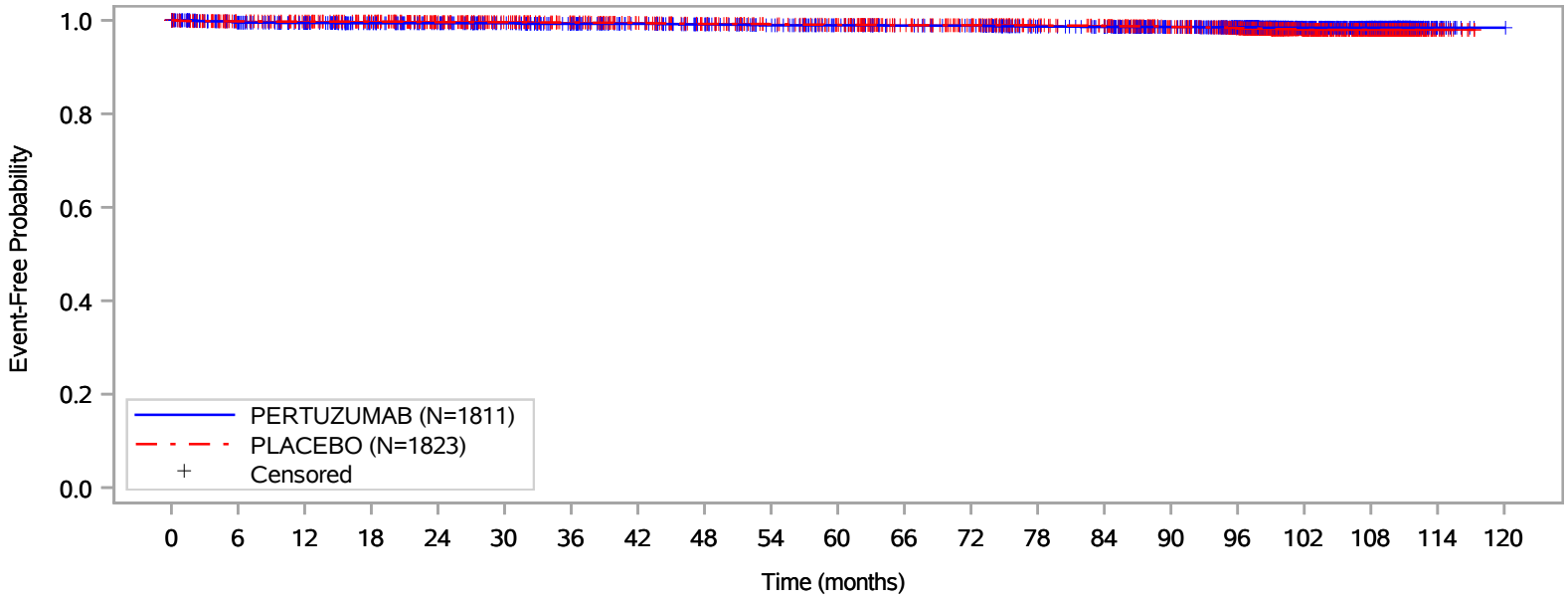


Patients at risk																					
PERTUZUMAB	1811	1743	1714	1674	1641	1609	1578	1548	1525	1502	1477	1453	1443	1400	1387	1315	1236	635	468	18	1
PLACEBO	1823	1766	1742	1704	1648	1604	1568	1528	1498	1471	1449	1401	1378	1331	1314	1254	1175	601	423	15	NE
Patients censored																					
PERTUZUMAB	0	59	73	85	90	103	108	121	134	147	156	168	173	210	219	282	357	953	1114	1562	1579
PLACEBO	0	46	56	68	78	86	96	113	121	129	139	171	181	216	226	273	345	910	1084	1489	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_DFSREC.pdf
04MAY2022 13:19

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Disease-free survival - Time to death
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

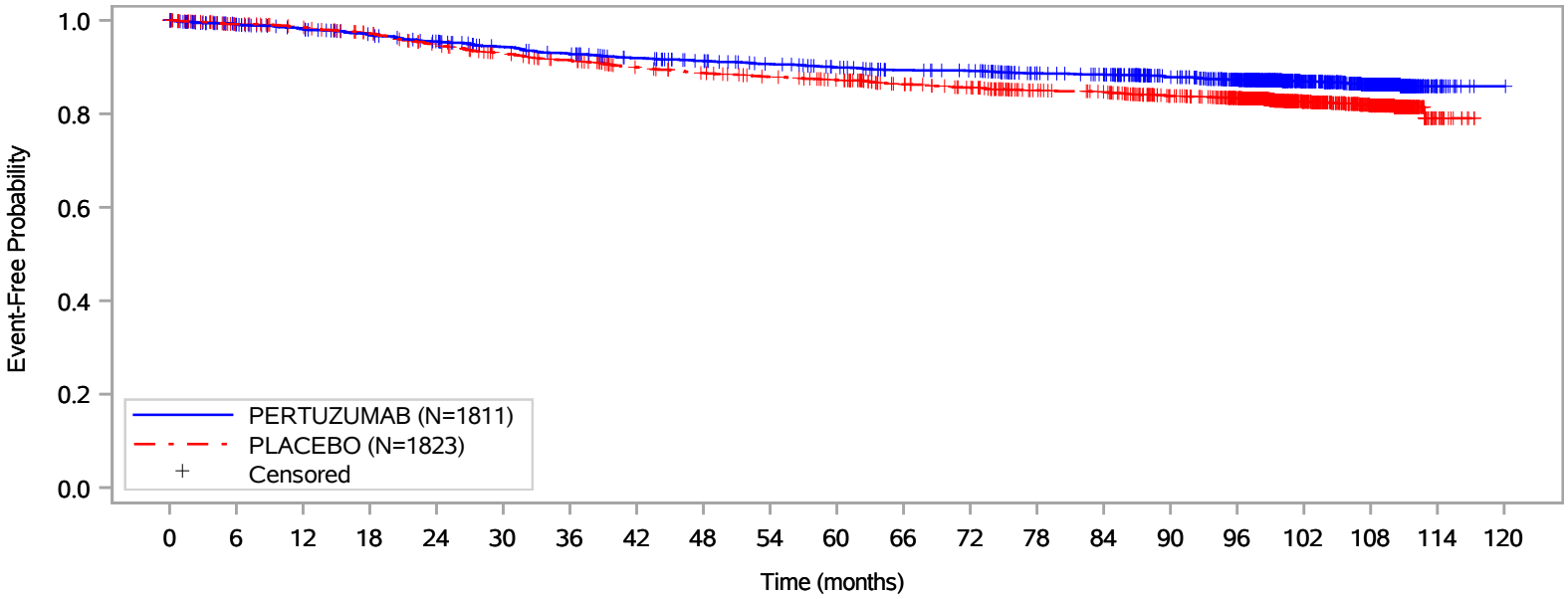


Patients at risk																						
PERTUZUMAB	1811	1743	1714	1674	1641	1609	1578	1548	1525	1502	1477	1453	1443	1400	1387	1315	1236	635	468	18	1	
PLACEBO	1823	1766	1742	1704	1648	1604	1568	1528	1498	1471	1449	1401	1378	1331	1314	1254	1175	601	423	15	NE	
Patients censored																						
PERTUZUMAB	0	59	87	126	159	191	220	250	271	291	316	339	349	389	401	473	552	1151	1318	1768	1785	
PLACEBO	0	53	76	114	168	212	247	285	312	338	358	405	428	475	490	547	623	1194	1372	1780	NE	

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_DFSDTH.pdf
04MAY2022 13:12

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Invasive disease-free survival
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

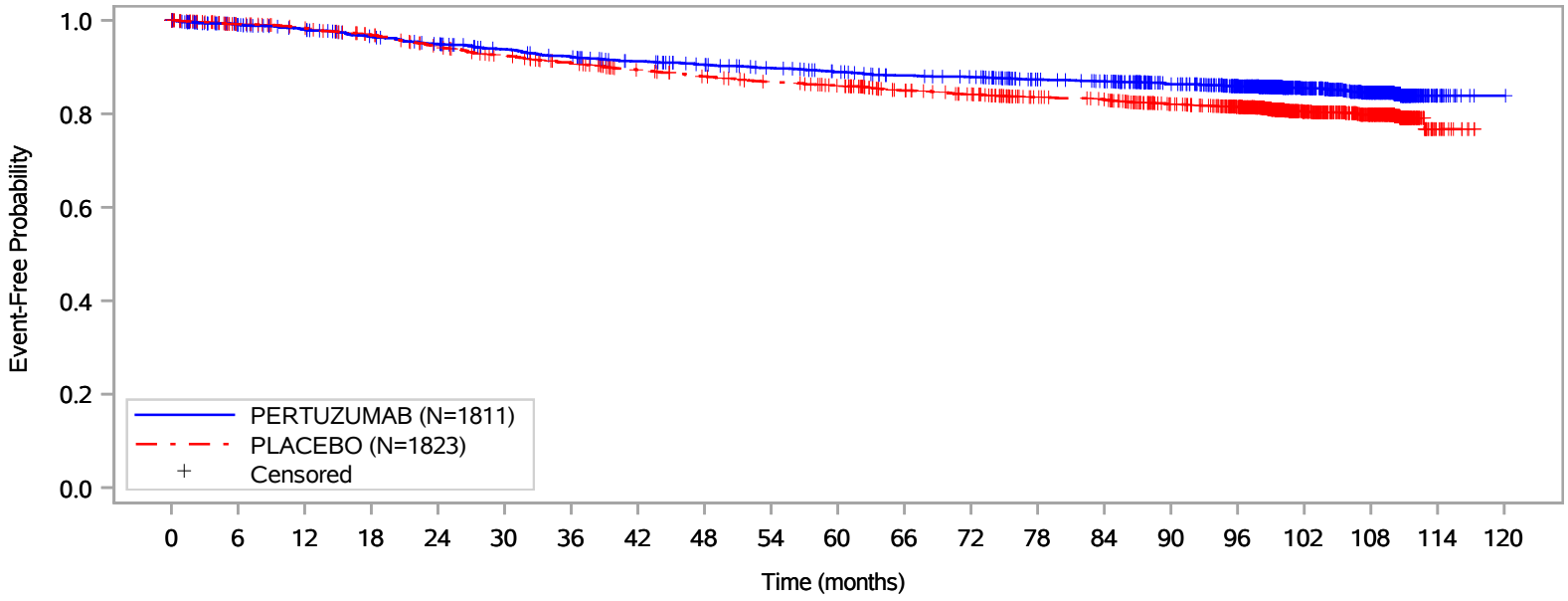


Patients at risk																					
PERTUZUMAB	1811	1744	1716	1682	1650	1616	1587	1558	1536	1514	1491	1468	1460	1417	1403	1328	1246	641	472	18	1
PLACEBO	1823	1766	1746	1711	1657	1616	1583	1541	1515	1492	1471	1424	1401	1354	1339	1280	1203	614	432	16	NE
Patients censored																					
PERTUZUMAB	0	51	64	75	82	96	99	113	125	136	146	160	166	200	210	276	351	951	1116	1569	1586
PLACEBO	0	42	51	63	71	81	90	106	111	120	130	161	173	210	220	265	335	916	1093	1507	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_IDFS.pdf
04MAY2022 12:27

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Invasive disease-free survival including second primary non-breast cancer
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All

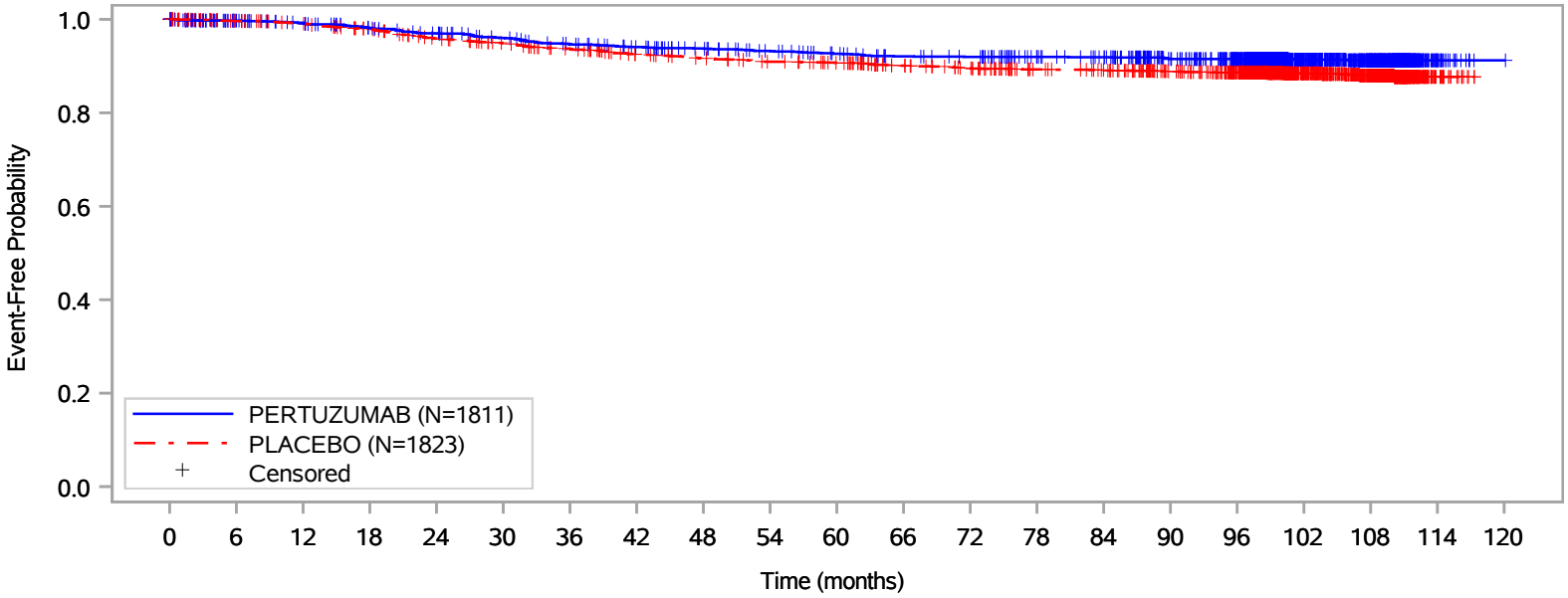


Patients at risk																					
PERTUZUMAB	1811	1744	1715	1676	1643	1611	1580	1551	1528	1506	1482	1459	1449	1406	1391	1318	1239	637	469	18	1
PLACEBO	1823	1766	1743	1705	1650	1610	1574	1534	1505	1478	1455	1407	1383	1338	1322	1262	1184	605	427	15	NE
Patients censored																					
PERTUZUMAB	0	50	63	74	79	92	95	108	119	129	138	149	154	188	197	260	334	930	1092	1541	1558
PLACEBO	0	42	51	63	71	79	88	103	108	115	124	155	166	201	209	253	322	890	1064	1473	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_IDFSS.pdf
04MAY2022 12:40

POPULATION: HR negative or node positive ITT
ENDPOINT: Time to first event, Distant recurrence-free interval
MODEL: --
STUDY: BO25126
Kaplan-Meier plot of time to first event (months)
Subgroup: All



Patients at risk																					
PERTUZUMAB	1811	1749	1727	1694	1667	1638	1607	1585	1564	1543	1523	1504	1497	1468	1457	1391	1320	700	503	23	1
PLACEBO	1823	1776	1757	1724	1677	1648	1615	1576	1555	1535	1521	1482	1461	1426	1414	1366	1297	669	476	24	NE
Patients censored																					
PERTUZUMAB	0	57	71	85	92	104	112	124	140	152	162	172	177	206	216	276	348	966	1162	1642	1664
PLACEBO	0	40	50	62	73	85	97	116	122	130	140	169	181	212	222	265	331	957	1147	1598	NE

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/g_eff_tte_km_26d_10JAN2022_CHON_DRFI.pdf
04MAY2022 13:20

Wirksamkeit (Datenschnitt: 10.01.2022)

Responder Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Recurrence/death rate
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Dichotomous analysis (efficacy)

		PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1811	100,0	256	14,1	1823	100,0	347	19,0	0,69		Algorithm converged.	0,58	0,83	-0,047		Algorithm converged.	-0,070	-0,024	0,74		Algorithm converged.	0,64	0,86	<.0001	1,35		Algorithm converged.	1,16	1,56

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_resp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_resp_26d_10JAN2022_CHON_RESP1_ST.xls
04MAY2022 12:55

Wirksamkeit (Datenschnitt: 10.01.2022)

Landmark Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Overall survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event landmark analysis

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients included in analysis	1811 (100%)		1823 (100%)
Patients with event (%)	140 (7.7%)		175 (9.6%)
Earliest contributing event			
DEATH	140		175
Patients without event (%)	1671 (92.3%)		1648 (90.4%)
Time to event (months)			
Median	NE		NE
95% CI	NE		NE
25% and 75%-ile	NE		NE
Range	0.0* - 120.1*		0.0* - 117.3*
Time point analysis			
0.5 year			
Patients remaining at risk	1753		1782
Event free proportion (%)	99,44		99,78
95% CI	(99.09, 99.78)		(99.56, 100.00)
1 year			
Patients remaining at risk	1739		1771
Event free proportion (%)	99,38		99,67
95% CI	(99.01, 99.74)		(99.40, 99.93)
1.5 years			
Patients remaining at risk	1720		1752
Event free proportion (%)	99,03		99,38
95% CI	(98.58, 99.49)		(99.02, 99.75)
2 years			
Patients remaining at risk	1704		1729
Event free proportion (%)	98,46		98,7
95% CI	(97.88, 99.03)		(98.17, 99.23)
2.5 years			
Patients remaining at risk	1682		1707
Event free proportion (%)	97,82		97,96
95% CI	(97.13, 98.50)		(97.29, 98.62)
3 years			

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients remaining at risk	1668		1684
Event free proportion (%)	97,18		97,15
95% CI	(96.40, 97.96)		(96.37, 97.93)
3.5 years			
Patients remaining at risk	1645		1650
Event free proportion (%)	96,42		96,11
95% CI	(95.54, 97.29)		(95.20, 97.01)
4 years			
Patients remaining at risk	1622		1629
Event free proportion (%)	95,83		95,23
95% CI	(94.89, 96.77)		(94.23, 96.23)
4.5 years			
Patients remaining at risk	1595		1616
Event free proportion (%)	94,94		94,82
95% CI	(93.90, 95.98)		(93.78, 95.86)
5 years			
Patients remaining at risk	1582		1594
Event free proportion (%)	94,7		94
95% CI	(93.64, 95.76)		(92.88, 95.12)
5.5 years			
Patients remaining at risk	1564		1556
Event free proportion (%)	94,22		93,34
95% CI	(93.11, 95.32)		(92.16, 94.52)
6 years			
Patients remaining at risk	1552		1536
Event free proportion (%)	93,92		92,8
95% CI	(92.78, 95.05)		(91.58, 94.02)
6.5 years			
Patients remaining at risk	1517		1499
Event free proportion (%)	93,37		92,25
95% CI	(92.19, 94.55)		(90.98, 93.51)
7 years			
Patients remaining at risk	1503		1481
Event free proportion (%)	93,06		91,57
95% CI	(91.85, 94.27)		(90.25, 92.89)
7.5 years			
Patients remaining at risk	1437		1435
Event free proportion (%)	92,49		91,19
95% CI	(91.23, 93.75)		(89.84, 92.54)
8 years			

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients remaining at risk	1358		1356
Event free proportion (%)	92,04		90,54
95% CI	(90.74, 93.33)		(89.15, 91.94)
8.5 years			
Patients remaining at risk	722		702
Event free proportion (%)	91,89		89,85
95% CI	(90.58, 93.20)		(88.38, 91.32)
Stratified analysis			
p-value (log-rank)		0,046	
Hazard ratio		0,798	
95% CI		(0.638, 0.996)	
Unstratified analysis			
p-value (log-rank)		0,0523	
Hazard ratio		0,803	
95% CI		(0.643, 1.003)	

* Censored observation.
Summaries of time to event (median, percentiles) are based on Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Hazard ratios were estimated by Cox regression.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_lma.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_lma_26d_10JAN2022_CHON_OS_ST.xls
04MAY2022 12:48

POPULATION: HR negative or node positive ITT
ENDPOINT: Disease-free survival
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Time to event landmark analysis

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
Patients included in analysis	1811 (100%)		1823 (100%)
Patients with event (%)	256 (14.1%)		347 (19.0%)
Earliest contributing event			
DEATH	25		28
DISEASE RECURRENCE	231		319
Patients without event (%)	1555 (85.9%)		1476 (81.0%)
Time to event (months)			
Median	NE		NE
95% CI	NE		NE
25% and 75%-ile	NE		NE
Range	0.0* - 120.1*		0.0* - 117.3*
Time point analysis			
0.5 year			
Patients remaining at risk	1743		1766
Event free proportion (%)	98,99		99,17
95% CI	(98.52, 99.45)		(98.74, 99.59)
1 year			
Patients remaining at risk	1714		1742
Event free proportion (%)	98,08		98,32
95% CI	(97.43, 98.72)		(97.72, 98.92)
1.5 years			
Patients remaining at risk	1674		1704
Event free proportion (%)	96,41		96,85
95% CI	(95.54, 97.28)		(96.04, 97.66)
2 years			
Patients remaining at risk	1641		1648
Event free proportion (%)	94,79		94,11
95% CI	(93.75, 95.84)		(93.02, 95.21)
2.5 years			
Patients remaining at risk	1609		1604
Event free proportion (%)	93,69		92,05
95% CI	(92.55, 94.83)		(90.79, 93.32)

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
3 years			
Patients remaining at risk	1578		1568
Event free proportion (%)	92,06		90,5
95% CI	(90.79, 93.33)		(89.13, 91.87)
3.5 years			
Patients remaining at risk	1548		1528
Event free proportion (%)	91,06		89,05
95% CI	(89.72, 92.41)		(87.59, 90.51)
4 years			
Patients remaining at risk	1525		1498
Event free proportion (%)	90,35		87,59
95% CI	(88.96, 91.75)		(86.04, 89.14)
4.5 years			
Patients remaining at risk	1502		1471
Event free proportion (%)	89,58		86,42
95% CI	(88.14, 91.02)		(84.81, 88.03)
5 years			
Patients remaining at risk	1477		1449
Event free proportion (%)	88,62		85,59
95% CI	(87.12, 90.12)		(83.94, 87.24)
5.5 years			
Patients remaining at risk	1453		1401
Event free proportion (%)	87,84		84,57
95% CI	(86.30, 89.39)		(82.87, 86.28)
6 years			
Patients remaining at risk	1443		1378
Event free proportion (%)	87,54		83,79
95% CI	(85.98, 89.10)		(82.05, 85.52)
6.5 years			
Patients remaining at risk	1400		1331
Event free proportion (%)	86,99		83,05
95% CI	(85.39, 88.58)		(81.28, 84.82)
7 years			
Patients remaining at risk	1387		1314
Event free proportion (%)	86,68		82,49
95% CI	(85.06, 88.29)		(80.69, 84.28)
7.5 years			
Patients remaining at risk	1315		1254
Event free proportion (%)	86,1		81,47
95% CI	(84.45, 87.74)		(79.63, 83.31)

	PERTUZUMAB (N=1811)		PLACEBO (N=1823)
8 years			
Patients remaining at risk	1236		1175
Event free proportion (%)	85,7		80,81
95% CI	(84.03, 87.36)		(78.94, 82.68)
8.5 years			
Patients remaining at risk	635		601
Event free proportion (%)	85,21		79,69
95% CI	(83.50, 86.93)		(77.73, 81.64)
Stratified analysis			
p-value (log-rank)		<.0001	
Hazard ratio		0,724	
95% CI		(0.615, 0.851)	
Unstratified analysis			
p-value (log-rank)		0,0001	
Hazard ratio		0,729	
95% CI		(0.620, 0.857)	

* Censored observation.
Summaries of time to event (median, percentiles) are based on Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Hazard ratios were estimated by Cox regression.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/eff_lma.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/eff_lma_26d_10JAN2022_CHON_DFS_ST.xls
04MAY2022 12:53

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Responder Analysen

Stratifiziert

MID = 15

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Fatigue Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	449	29,2	1597	87,6	375	23,5	1,35		Algorithm converged.	1,15	1,58	0,057		Algorithm converged.	0,027	0,088		1,246		Algorithm converged.	1,108	1,402	0,0003	0,803		Algorithm converged.	0,713	0,903
FU MONTH 36	All	n/a	1361	75,2	245	18,0	1327	72,8	271	20,4	0,86		Algorithm converged.	0,71	1,04	-0,024		Algorithm converged.	-0,054	0,005		0,882		Algorithm converged.	0,755	1,030	0,1125	1,134		Algorithm converged.	0,971	1,324

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC01_W15_ST.xls
26OCT2020 15:06

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1542	85,1	184	11,9	1598	87,7	176	11,0	1,10		Algorithm converged.	0,88	1,37	0,008		Algorithm converged.	-0,014	0,030	1,085		Algorithm converged.	0,893	1,317	0,4105	0,922		Algorithm converged.	0,759	1,119
FU MONTH 36	All	n/a	1363	75,3	125	9,2	1328	72,8	132	9,9	0,91		Algorithm converged.	0,70	1,17	-0,007		Algorithm converged.	-0,029	0,015	0,915		Algorithm converged.	0,726	1,154	0,4531	1,093		Algorithm converged.	0,867	1,378

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC02_W15_ST.xls
26OCT2020 15:08

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Pain Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1541	85,1	420	27,3	1597	87,6	461	28,9	0,92		Algorithm converged.	0,79	1,08	-0,017		Algorithm converged.	-0,048	0,015	0,942		Algorithm converged.	0,842	1,054	0,2968	1,061		Algorithm converged.	0,949	1,187
FU MONTH 36	All	n/a	1362	75,2	316	23,2	1328	72,8	318	23,9	0,96		Algorithm converged.	0,80	1,15	-0,007		Algorithm converged.	-0,039	0,025	0,968		Algorithm converged.	0,845	1,110	0,6431	1,033		Algorithm converged.	0,901	1,183

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC03_W15_ST.xls
26OCT2020 15:10

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Dyspnea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1539	85,0	392	25,5	1592	87,3	375	23,6	1,11		Algorithm converged.	0,94	1,31	0,020		Algorithm converged.	-0,010	0,050		1,081		Algorithm converged.	0,956	1,223	0,2137	0,925		Algorithm converged.	0,818	1,046
FU MONTH 36	All	n/a	1361	75,2	278	20,4	1321	72,5	303	22,9	0,87		Algorithm converged.	0,72	1,04	-0,026		Algorithm converged.	-0,057	0,005		0,896		Algorithm converged.	0,776	1,034	0,1329	1,117		Algorithm converged.	0,967	1,289

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC04_W15_ST.xls
26OCT2020 15:12

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Insomnia Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	430	28,0	1591	87,3	405	25,5	1,14		Algorithm converged.	0,97	1,34	0,025		Algorithm converged.	-0,006	0,056	1,101		Algorithm converged.	0,980	1,237	0,1040	0,908		Algorithm converged.	0,809	1,020
FU MONTH 36	All	n/a	1362	75,2	318	23,3	1322	72,5	333	25,2	0,91		Algorithm converged.	0,76	1,08	-0,019		Algorithm converged.	-0,051	0,014	0,929		Algorithm converged.	0,813	1,062	0,2790	1,077		Algorithm converged.	0,942	1,231

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC05_W15_ST.xls
26OCT2020 15:14

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Appetite Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	235	15,3	1594	87,4	180	11,3	1,42		Algorithm converged.	1,15	1,75	0,042		Algorithm converged.	0,018	0,066	1,353		Algorithm converged.	1,129	1,621	0,0011	0,739		Algorithm converged.	0,617	0,886
FU MONTH 36	All	n/a	1361	75,2	121	8,9	1326	72,7	125	9,4	0,94		Algorithm converged.	0,73	1,23	-0,003		Algorithm converged.	-0,025	0,018	0,946		Algorithm converged.	0,746	1,200	0,6472	1,057		Algorithm converged.	0,833	1,341

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC06_W15_ST.xls
26OCT2020 15:17

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Constipation Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	202	13,1	1593	87,4	248	15,6	0,82		Algorithm converged.	0,67	1,00	-0,025		Algorithm converged.	-0,050	-0,001	0,845		Algorithm converged.	0,711	1,003	0,0546	1,184		Algorithm converged.	0,997	1,406
FU MONTH 36	All	n/a	1363	75,3	219	16,1	1321	72,5	201	15,2	1,07		Algorithm converged.	0,86	1,31	0,007		Algorithm converged.	-0,021	0,035	1,057		Algorithm converged.	0,887	1,260	0,5372	0,946		Algorithm converged.	0,794	1,128

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC07_W15_ST.xls
26OCT2020 15:19

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Diarrhea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	458	29,9	1590	87,2	213	13,4	2,76		Algorithm converged.	2,30	3,31	0,166		Algorithm converged.	0,138	0,194	2,228		Algorithm converged.	1,924	2,579	<.0001	0,449		Algorithm converged.	0,388	0,520
FU MONTH 36	All	n/a	1358	75,0	100	7,4	1322	72,5	128	9,7	0,74		Algorithm converged.	0,56	0,97	-0,025		Algorithm converged.	-0,046	-0,004	0,759		Algorithm converged.	0,591	0,975	0,0308	1,318		Algorithm converged.	1,026	1,693

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC08_W15_ST.xls
26OCT2020 15:21

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Financial Difficulties Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1524	84,2	255	16,7	1586	87,0	276	17,4	0,96		Algorithm converged.	0,80	1,16	-0,004		Algorithm converged.	-0,031	0,022	0,964		Algorithm converged.	0,825	1,125	0,6382	1,038		Algorithm converged.	0,889	1,212
FU MONTH 36	All	n/a	1351	74,6	151	11,2	1321	72,5	146	11,1	1,01		Algorithm converged.	0,79	1,29	0,005		Algorithm converged.	-0,019	0,029	1,002		Algorithm converged.	0,809	1,241	0,9830	0,998		Algorithm converged.	0,805	1,236

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC09_W15_ST.xls
26OCT2020 15:24

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Global Health Status
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	428	27,9	1589	87,2	421	26,5	1,07		Algorithm converged.	0,92	1,26	0,015		Algorithm converged.	-0,016	0,047	1,049		Algorithm converged.	0,935	1,176	0,4158	0,954		Algorithm converged.	0,850	1,069
FU MONTH 36	All	n/a	1357	74,9	295	21,7	1320	72,4	320	24,2	0,87		Algorithm converged.	0,72	1,04	-0,024		Algorithm converged.	-0,056	0,008	0,892		Algorithm converged.	0,776	1,025	0,1061	1,121		Algorithm converged.	0,976	1,288

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_GLHST_W15_ST.xls
26OCT2020 15:03

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Physical Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1543	85,2	203	13,2	1597	87,6	196	12,3	1,09		Algorithm converged.	0,88	1,34	0,009		Algorithm converged.	-0,014	0,032		1,078		Algorithm converged.	0,897	1,294	0,4234	0,928		Algorithm converged.	0,773	1,114
FU MONTH 36	All	n/a	1363	75,3	121	8,9	1329	72,9	111	8,4	1,07		Algorithm converged.	0,82	1,40	0,005		Algorithm converged.	-0,017	0,026		1,061		Algorithm converged.	0,830	1,357	0,6372	0,943		Algorithm converged.	0,737	1,205

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC01_W15_ST.xls
26OCT2020 14:44

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Role Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1540	85,0	383	24,9	1594	87,4	368	23,1	1,11		Algorithm converged.	0,94	1,30	0,018		Algorithm converged.	-0,012	0,048	1,081		Algorithm converged.	0,954	1,224	0,2205	0,925		Algorithm converged.	0,817	1,048
FU MONTH 36	All	n/a	1362	75,2	216	15,9	1327	72,8	243	18,3	0,84		Algorithm converged.	0,69	1,03	-0,026		Algorithm converged.	-0,054	0,002	0,868		Algorithm converged.	0,735	1,026	0,0975	1,152		Algorithm converged.	0,975	1,361

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC02_W15_ST.xls
26OCT2020 14:46

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Emotional Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	200	13,0	1593	87,4	230	14,4	0,89		Algorithm converged.	0,72	1,09	-0,012		Algorithm converged.	-0,036	0,012		0,902		Algorithm converged.	0,756	1,075	0,2498	1,109		Algorithm converged.	0,930	1,322
FU MONTH 36	All	n/a	1359	75,0	162	11,9	1324	72,6	177	13,4	0,88		Algorithm converged.	0,70	1,10	-0,016		Algorithm converged.	-0,041	0,009		0,893		Algorithm converged.	0,732	1,089	0,2626	1,120		Algorithm converged.	0,918	1,367

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC03_W15_ST.xls
26OCT2020 14:48

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1536	84,8	607	39,5	1592	87,3	632	39,7	0,99		Algorithm converged.	0,86	1,15	-0,001		Algorithm converged.	-0,035	0,034	0,996		Algorithm converged.	0,913	1,086	0,9228	1,004		Algorithm converged.	0,921	1,095
FU MONTH 36	All	n/a	1360	75,1	490	36,0	1324	72,6	494	37,3	0,94		Algorithm converged.	0,81	1,11	-0,012		Algorithm converged.	-0,049	0,024	0,961		Algorithm converged.	0,871	1,062	0,4358	1,040		Algorithm converged.	0,942	1,149

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC04_W15_ST.xls
26OCT2020 14:50

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Social Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	349	22,7	1590	87,2	376	23,6	0,95		Algorithm converged.	0,81	1,12	-0,008		Algorithm converged.	-0,037	0,022	0,961		Algorithm converged.	0,846	1,092	0,5395	1,041		Algorithm converged.	0,916	1,182
FU MONTH 36	All	n/a	1360	75,1	209	15,4	1323	72,6	237	17,9	0,84		Algorithm converged.	0,68	1,02	-0,025		Algorithm converged.	-0,053	0,003	0,861		Algorithm converged.	0,727	1,021	0,0845	1,161		Algorithm converged.	0,980	1,376

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC05_W15_ST.xls
26OCT2020 14:52

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	268	17,5	1591	87,3	252	15,8	1,14		Algorithm converged.	0,94	1,37	0,017		Algorithm converged.	-0,009	0,043	1,111		Algorithm converged.	0,950	1,299	0,1885	0,900		Algorithm converged.	0,770	1,053
FU MONTH 36	All	n/a	1358	75,0	182	13,4	1321	72,5	198	15,0	0,88		Algorithm converged.	0,71	1,09	-0,014		Algorithm converged.	-0,040	0,012	0,893		Algorithm converged.	0,741	1,076	0,2334	1,120		Algorithm converged.	0,930	1,349

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC10_W15_ST.xls
26OCT2020 15:26

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	292	19,1	1580	86,7	245	15,5	1,29		Algorithm converged.	1,07	1,55	0,035		Algorithm converged.	0,008	0,062		1,234		Algorithm converged.	1,057	1,440	0,0077	0,811		Algorithm converged.	0,694	0,946
FU MONTH 36	All	n/a	1355	74,8	154	11,4	1318	72,3	141	10,7	1,07		Algorithm converged.	0,84	1,37	0,010		Algorithm converged.	-0,014	0,034		1,058		Algorithm converged.	0,853	1,312	0,6097	0,945		Algorithm converged.	0,762	1,173

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC11_W15_ST.xls
26OCT2020 15:28

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	201	13,1	1581	86,7	228	14,4	0,89		Algorithm converged.	0,73	1,10	-0,013		Algorithm converged.	-0,037	0,011	0,908		Algorithm converged.	0,761	1,082	0,2804	1,102		Algorithm converged.	0,924	1,313
FU MONTH 36	All	n/a	1355	74,8	176	13,0	1320	72,4	176	13,3	0,97		Algorithm converged.	0,77	1,21	0,000		Algorithm converged.	-0,025	0,026	0,964		Algorithm converged.	0,794	1,170	0,7072	1,038		Algorithm converged.	0,855	1,260

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC12_W15_ST.xls
26OCT2020 15:31

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	57	3,1	10	17,5	54	3,0	16	29,6	0,28		Algorithm converged.	0,09	0,88	-0,119	*	WARNING: The relative Hessian convergence criterion of 0.2816016161 is greater than the limit of 0.0001. The convergence is questionable.	-0,337	0,099		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
FU MONTH 36	All	n/a	73	4,0	18	24,7	77	4,2	20	26,0	0,75		Algorithm converged.	0,34	1,67	-0,097	*	WARNING: The relative Hessian convergence criterion of 0.0005039016 is greater than the limit of 0.0001. The convergence is questionable.	-0,253	0,059		0,893		Algorithm converged.	0,505	1,578	0,6961	1,120		Algorithm converged.	0,634	1,981

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC13_W15_ST.xls
26OCT2020 15:33

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Body Image Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1521	84,0	406	26,7	1573	86,3	469	29,8	0,86		Algorithm converged.	0,73	1,01	-0,032		Algorithm converged.	-0,064	-0,001	0,900		Algorithm converged.	0,804	1,007	0,0654	1,111		Algorithm converged.	0,993	1,244
FU MONTH 36	All	n/a	1342	74,1	271	20,2	1304	71,5	298	22,9	0,85		Algorithm converged.	0,71	1,03	-0,026		Algorithm converged.	-0,057	0,005	0,883		Algorithm converged.	0,764	1,022	0,0947	1,132		Algorithm converged.	0,979	1,309

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC06_W15_ST.xls
26OCT2020 14:55

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1456	80,4	336	23,1	1509	82,8	358	23,7	0,96		Algorithm converged.	0,81	1,14	-0,007		Algorithm converged.	-0,037	0,024		0,973		Algorithm converged.	0,854	1,108	0,6797	1,028		Algorithm converged.	0,902	1,171
FU MONTH 36	All	n/a	1279	70,6	258	20,2	1251	68,6	269	21,5	0,92		Algorithm converged.	0,76	1,11	-0,014		Algorithm converged.	-0,045	0,018		0,934		Algorithm converged.	0,802	1,087	0,3767	1,071		Algorithm converged.	0,920	1,247

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC07_W15_ST.xls
26OCT2020 14:57

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Enjoyment Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	437	24,1	147	33,6	481	26,4	159	33,1	1,02		Algorithm converged.	0,78	1,35	0,004		Algorithm converged.	-0,057	0,065	1,020		Algorithm converged.	0,849	1,226	0,8293	0,980		Algorithm converged.	0,816	1,177
FU MONTH 36	All	n/a	383	21,1	113	29,5	402	22,1	118	29,4	1,02		Algorithm converged.	0,75	1,39	-0,002		Algorithm converged.	-0,066	0,062	1,025		Algorithm converged.	0,825	1,274	0,8224	0,975		Algorithm converged.	0,785	1,212

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC08_W15_ST.xls
26OCT2020 14:59

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Future Perspective Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1518	83,8	272	17,9	1576	86,5	292	18,5	0,96		Algorithm converged.	0,80	1,15	-0,010		Algorithm converged.	-0,037	0,016	0,971		Algorithm converged.	0,837	1,127	0,6971	1,030		Algorithm converged.	0,888	1,195
FU MONTH 36	All	n/a	1340	74,0	191	14,3	1304	71,5	188	14,4	0,98		Algorithm converged.	0,79	1,22	-0,005		Algorithm converged.	-0,032	0,022	0,990		Algorithm converged.	0,822	1,193	0,9183	1,010		Algorithm converged.	0,838	1,216

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC09_W15_ST.xls
26OCT2020 15:01

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Responder Analysen

Stratifiziert

MID = 10

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Fatigue Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	703	45,7	1597	87,6	642	40,2	1,26		Algorithm converged.	1,09	1,45	0,056		Algorithm converged.	0,021	0,090	1,14		Algorithm converged.	1,05	1,24	0,0014	0,88		Algorithm converged.	0,81	0,95
FU MONTH 36	All	n/a	1361	75,2	437	32,1	1327	72,8	474	35,7	0,85		Algorithm converged.	0,73	1,00	-0,036		Algorithm converged.	-0,072	0,000	0,90		Algorithm converged.	0,81	1,00	0,0539	1,11		Algorithm converged.	1,00	1,23

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC01_W10_ST.xls
30JUL2020 16:10

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1542	85,1	184	11,9	1598	87,7	176	11,0	1,10		Algorithm converged.	0,88	1,37	0,008		Algorithm converged.	-0,014	0,030	1,08		Algorithm converged.	0,89	1,32	0,4105	0,92		Algorithm converged.	0,76	1,12
FU MONTH 36	All	n/a	1363	75,3	125	9,2	1328	72,8	132	9,9	0,91		Algorithm converged.	0,70	1,17	-0,007		Algorithm converged.	-0,029	0,015	0,92		Algorithm converged.	0,73	1,15	0,4531	1,09		Algorithm converged.	0,87	1,38

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC02_W10_ST.xls
30JUL2020 16:13

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Pain Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1541	85,1	420	27,3	1597	87,6	461	28,9	0,92		Algorithm converged.	0,79	1,08	-0,017		Algorithm converged.	-0,048	0,015	0,94		Algorithm converged.	0,84	1,05	0,2968	1,06		Algorithm converged.	0,95	1,19
FU MONTH 36	All	n/a	1362	75,2	316	23,2	1328	72,8	318	23,9	0,96		Algorithm converged.	0,80	1,15	-0,007		Algorithm converged.	-0,039	0,025	0,97		Algorithm converged.	0,84	1,11	0,6431	1,03		Algorithm converged.	0,90	1,18

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC03_W10_ST.xls
30JUL2020 16:16

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Dyspnea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1539	85,0	392	25,5	1592	87,3	375	23,6	1,11		Algorithm converged.	0,94	1,31	0,020		Algorithm converged.	-0,010	0,050	1,08		Algorithm converged.	0,96	1,22	0,2137	0,92		Algorithm converged.	0,82	1,05
FU MONTH 36	All	n/a	1361	75,2	278	20,4	1321	72,5	303	22,9	0,87		Algorithm converged.	0,72	1,04	-0,026		Algorithm converged.	-0,057	0,005	0,90		Algorithm converged.	0,78	1,03	0,1329	1,12		Algorithm converged.	0,97	1,29

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC04_W10_ST.xls
30JUL2020 16:18

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Insomnia Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	430	28,0	1591	87,3	405	25,5	1,14		Algorithm converged.	0,97	1,34	0,025		Algorithm converged.	-0,006	0,056	1,10		Algorithm converged.	0,98	1,24	0,1040	0,91		Algorithm converged.	0,81	1,02
FU MONTH 36	All	n/a	1362	75,2	318	23,3	1322	72,5	333	25,2	0,91		Algorithm converged.	0,76	1,08	-0,019		Algorithm converged.	-0,051	0,014	0,93		Algorithm converged.	0,81	1,06	0,2790	1,08		Algorithm converged.	0,94	1,23

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC05_W10_ST.xls
30JUL2020 16:21

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Appetite Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	235	15,3	1594	87,4	180	11,3	1,42		Algorithm converged.	1,15	1,75	0,042		Algorithm converged.	0,018	0,066	1,35		Algorithm converged.	1,13	1,62	0,0011	0,74		Algorithm converged.	0,62	0,89
FU MONTH 36	All	n/a	1361	75,2	121	8,9	1326	72,7	125	9,4	0,94		Algorithm converged.	0,73	1,23	-0,003		Algorithm converged.	-0,025	0,018	0,95		Algorithm converged.	0,75	1,20	0,6472	1,06		Algorithm converged.	0,83	1,34

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC06_W10_ST.xls
30JUL2020 16:23

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Constipation Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	202	13,1	1593	87,4	248	15,6	0,82		Algorithm converged.	0,67	1,00	-0,025		Algorithm converged.	-0,050	-0,001	0,84		Algorithm converged.	0,71	1,00	0,0546	1,18		Algorithm converged.	1,00	1,41
FU MONTH 36	All	n/a	1363	75,3	219	16,1	1321	72,5	201	15,2	1,07		Algorithm converged.	0,86	1,31	0,007		Algorithm converged.	-0,021	0,035	1,06		Algorithm converged.	0,89	1,26	0,5372	0,95		Algorithm converged.	0,79	1,13

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC07_W10_ST.xls
30JUL2020 16:25

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Diarrhea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	458	29,9	1590	87,2	213	13,4	2,76		Algorithm converged.	2,30	3,31	0,166		Algorithm converged.	0,138	0,194	2,23		Algorithm converged.	1,92	2,58	<.0001	0,45		Algorithm converged.	0,39	0,52
FU MONTH 36	All	n/a	1358	75,0	100	7,4	1322	72,5	128	9,7	0,74		Algorithm converged.	0,56	0,97	-0,025		Algorithm converged.	-0,046	-0,004	0,76		Algorithm converged.	0,59	0,97	0,0308	1,32		Algorithm converged.	1,03	1,69

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC08_W10_ST.xls
30JUL2020 16:27

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Financial Difficulties Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1524	84,2	255	16,7	1586	87,0	276	17,4	0,96		Algorithm converged.	0,80	1,16	-0,004		Algorithm converged.	-0,031	0,022	0,96		Algorithm converged.	0,83	1,12	0,6382	1,04		Algorithm converged.	0,89	1,21
FU MONTH 36	All	n/a	1351	74,6	151	11,2	1321	72,5	146	11,1	1,01		Algorithm converged.	0,79	1,29	0,005		Algorithm converged.	-0,019	0,029	1,00		Algorithm converged.	0,81	1,24	0,9830	1,00		Algorithm converged.	0,81	1,24

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC09_W10_ST.xls
30JUL2020 16:30

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Global Health Status
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	428	27,9	1589	87,2	421	26,5	1,07		Algorithm converged.	0,92	1,26	0,015		Algorithm converged.	-0,016	0,047	1,05		Algorithm converged.	0,94	1,18	0,4158	0,95		Algorithm converged.	0,85	1,07
FU MONTH 36	All	n/a	1357	74,9	295	21,7	1320	72,4	320	24,2	0,87		Algorithm converged.	0,72	1,04	-0,024		Algorithm converged.	-0,056	0,008	0,89		Algorithm converged.	0,78	1,02	0,1061	1,12		Algorithm converged.	0,98	1,29

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_GLHST_W10_ST.xls
30JUL2020 16:08

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Physical Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1543	85,2	358	23,2	1597	87,6	361	22,6	1,04		Algorithm converged.	0,88	1,23	0,007		Algorithm converged.	-0,022	0,037	1,03		Algorithm converged.	0,90	1,17	0,6641	0,97		Algorithm converged.	0,85	1,10
FU MONTH 36	All	n/a	1363	75,3	236	17,3	1329	72,9	234	17,6	0,98		Algorithm converged.	0,80	1,19	-0,001		Algorithm converged.	-0,030	0,028	0,98		Algorithm converged.	0,83	1,15	0,7995	1,02		Algorithm converged.	0,87	1,20

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC01_W10_ST.xls
30JUL2020 15:43

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Role Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1540	85,0	383	24,9	1594	87,4	368	23,1	1,11		Algorithm converged.	0,94	1,30	0,018		Algorithm converged.	-0,012	0,048	1,08		Algorithm converged.	0,95	1,22	0,2205	0,93		Algorithm converged.	0,82	1,05
FU MONTH 36	All	n/a	1362	75,2	216	15,9	1327	72,8	243	18,3	0,84		Algorithm converged.	0,69	1,03	-0,026		Algorithm converged.	-0,054	0,002	0,87		Algorithm converged.	0,73	1,03	0,0975	1,15		Algorithm converged.	0,97	1,36

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC02_W10_ST.xls
30JUL2020 15:45

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Emotional Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	388	25,3	1593	87,4	393	24,7	1,03		Algorithm converged.	0,88	1,21	0,007		Algorithm converged.	-0,024	0,037	1,023		Algorithm converged.	0,906	1,155	0,7147	0,978		Algorithm converged.	0,866	1,104
FU MONTH 36	All	n/a	1359	75,0	302	22,2	1324	72,6	337	25,5	0,84		Algorithm converged.	0,70	1,00	-0,031		Algorithm converged.	-0,064	0,001	0,872		Algorithm converged.	0,761	0,998	0,0469	1,147		Algorithm converged.	1,002	1,314

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC03_W10_ST.xls
13AUG2020 15:20

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1536	84,8	607	39,5	1592	87,3	632	39,7	0,99		Algorithm converged.	0,86	1,15	-0,001		Algorithm converged.	-0,035	0,034	1,00		Algorithm converged.	0,91	1,09	0,9228	1,00		Algorithm converged.	0,92	1,09
FU MONTH 36	All	n/a	1360	75,1	490	36,0	1324	72,6	494	37,3	0,94		Algorithm converged.	0,81	1,11	-0,012		Algorithm converged.	-0,049	0,024	0,96		Algorithm converged.	0,87	1,06	0,4358	1,04		Algorithm converged.	0,94	1,15

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC04_W10_ST.xls
30JUL2020 15:49

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Social Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version; region)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	349	22,7	1590	87,2	376	23,6	0,95		Algorithm converged.	0,81	1,12	-0,008		Algorithm converged.	-0,037	0,022	0,96		Algorithm converged.	0,85	1,09	0,5395	1,04		Algorithm converged.	0,92	1,18
FU MONTH 36	All	n/a	1360	75,1	209	15,4	1323	72,6	237	17,9	0,84		Algorithm converged.	0,68	1,02	-0,025		Algorithm converged.	-0,053	0,003	0,86		Algorithm converged.	0,73	1,02	0,0845	1,16		Algorithm converged.	0,98	1,38

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC05_W10_ST.xls
30JUL2020 15:54

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	416	27,1	1591	87,3	426	26,8	1,02		Algorithm converged.	0,87	1,20	0,003		Algorithm converged.	-0,028	0,034	1,020		Algorithm converged.	0,909	1,144	0,7422	0,981		Algorithm converged.	0,874	1,101
FU MONTH 36	All	n/a	1358	75,0	313	23,0	1321	72,5	318	24,1	0,94		Algorithm converged.	0,79	1,13	-0,009		Algorithm converged.	-0,041	0,023	0,956		Algorithm converged.	0,835	1,096	0,5217	1,045		Algorithm converged.	0,912	1,198

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC10_W10_ST.xls
03SEP2020 0:10

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	292	19,1	1580	86,7	246	15,6	1,28		Algorithm converged.	1,06	1,54	0,034		Algorithm converged.	0,008	0,061	1,229		Algorithm converged.	1,053	1,434	0,0090	0,814		Algorithm converged.	0,698	0,950
FU MONTH 36	All	n/a	1355	74,8	154	11,4	1318	72,3	141	10,7	1,07		Algorithm converged.	0,84	1,37	0,010		Algorithm converged.	-0,014	0,034	1,058		Algorithm converged.	0,853	1,312	0,6097	0,945		Algorithm converged.	0,762	1,173

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC11_W10_ST.xls
03SEP2020 0:12

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	417	27,2	1581	86,7	454	28,7	0,92		Algorithm converged.	0,79	1,08	-0,014		Algorithm converged.	-0,046	0,017	0,942		Algorithm converged.	0,841	1,054	0,2957	1,062		Algorithm converged.	0,949	1,188
FU MONTH 36	All	n/a	1355	74,8	320	23,6	1320	72,4	336	25,5	0,90		Algorithm converged.	0,76	1,08	-0,017		Algorithm converged.	-0,049	0,016	0,921		Algorithm converged.	0,807	1,052	0,2266	1,085		Algorithm converged.	0,950	1,240

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC12_W10_ST.xls
03SEP2020 0:14

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	57	3,1	10	17,5	54	3,0	16	29,6	0,28		Algorithm converged.	0,09	0,88	-0,119	*	WARNING: The relative Hessian convergence criterion of 0.2816016161 is greater than the limit of 0.0001. The convergence is questionable.	-0,337	0,099	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
FU MONTH 36	All	n/a	73	4,0	18	24,7	77	4,2	20	26,0	0,75		Algorithm converged.	0,34	1,67	-0,097	*	WARNING: The relative Hessian convergence criterion of 0.0005039016 is greater than the limit of 0.0001. The convergence is questionable.	-0,253	0,059	0,893		Algorithm converged.	0,505	1,578	0,6961	1,120		Algorithm converged.	0,634	1,981

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC13_W10_ST.xls
03SEP2020 0:15

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Body Image Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1521	84,0	407	26,8	1573	86,3	472	30,0	0,85		Algorithm converged.	0,73	1,00	-0,033		Algorithm converged.	-0,065	-0,002	0,896		Algorithm converged.	0,801	1,003	0,0559	1,116		Algorithm converged.	0,997	1,248
FU MONTH 36	All	n/a	1342	74,1	272	20,3	1304	71,5	300	23,0	0,85		Algorithm converged.	0,71	1,02	-0,027		Algorithm converged.	-0,059	0,004	0,881		Algorithm converged.	0,762	1,018	0,0862	1,135		Algorithm converged.	0,982	1,313

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC06_W10_ST.xls
02SEP2020 23:44

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1456	80,4	336	23,1	1509	82,8	358	23,7	0,96		Algorithm converged.	0,81	1,14	-0,007		Algorithm converged.	-0,037	0,024	0,973		Algorithm converged.	0,854	1,108	0,6797	1,028		Algorithm converged.	0,902	1,171
FU MONTH 36	All	n/a	1279	70,6	258	20,2	1251	68,6	269	21,5	0,92		Algorithm converged.	0,76	1,11	-0,014		Algorithm converged.	-0,045	0,018	0,934		Algorithm converged.	0,802	1,087	0,3767	1,071		Algorithm converged.	0,920	1,247

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC07_W10_ST.xls
02SEP2020 23:46

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Enjoyment Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	437	24,1	147	33,6	481	26,4	159	33,1	1,02		Algorithm converged.	0,78	1,35	0,004		Algorithm converged.	-0,057	0,065	1,020		Algorithm converged.	0,849	1,226	0,8293	0,980		Algorithm converged.	0,816	1,177
FU MONTH 36	All	n/a	383	21,1	113	29,5	402	22,1	118	29,4	1,02		Algorithm converged.	0,75	1,39	-0,002		Algorithm converged.	-0,066	0,062	1,025		Algorithm converged.	0,825	1,274	0,8224	0,975		Algorithm converged.	0,785	1,212

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC08_W10_ST.xls
02SEP2020 23:48

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Future Perspective Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Responder Analysis: 10-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1518	83,8	272	17,9	1576	86,5	292	18,5	0,96		Algorithm converged.	0,80	1,15	-0,010		Algorithm converged.	-0,037	0,016	0,971		Algorithm converged.	0,837	1,127	0,6971	1,030		Algorithm converged.	0,888	1,195
FU MONTH 36	All	n/a	1340	74,0	191	14,3	1304	71,5	188	14,4	0,98		Algorithm converged.	0,79	1,22	-0,005		Algorithm converged.	-0,032	0,022	0,990		Algorithm converged.	0,822	1,193	0,9183	1,010		Algorithm converged.	0,838	1,216

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC09_W10_ST.xls
02SEP2020 23:49

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Responder Analysen

Unstratifiziert + Subgruppen

MID = 15

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Fatigue Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	449	29,2	1597	87,6	375	23,5	1,34		Algorithm converged.	1,15	1,58	0,057		Algorithm converged.	0,026	0,088	1,243		Algorithm converged.	1,105	1,399	0,0003		0,804		Algorithm converged.	0,715	0,905
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	14	32,6	35	1,9	10	28,6	1,21		Algorithm converged.	0,46	3,19	0,040		Algorithm converged.	-0,165	0,245	1,140		Algorithm converged.	0,579	2,244	0,7057	0,7067	0,878		Algorithm converged.	0,446	1,728
		0 positive nodes, tumor > 1 cm	225	12,4	76	33,8	248	13,6	70	28,2	1,30		Algorithm converged.	0,88	1,92	0,056		Algorithm converged.	-0,028	0,139	1,197		Algorithm converged.	0,914	1,568	0,1923		0,836		Algorithm converged.	0,638	1,095
		1-3 positive nodes	769	42,5	218	28,3	796	43,7	190	23,9	1,26		Algorithm converged.	1,01	1,58	0,045		Algorithm converged.	0,001	0,088	1,188		Algorithm converged.	1,005	1,404	0,0440		0,842		Algorithm converged.	0,712	0,995
		>= 4 positive nodes	501	27,7	141	28,1	518	28,4	105	20,3	1,54		Algorithm converged.	1,15	2,06	0,079		Algorithm converged.	0,026	0,131	1,388		Algorithm converged.	1,113	1,731	0,0036		0,720		Algorithm converged.	0,578	0,898
	Adjuvant chemotherapy regimen	Anthracycline	1231	68,0	365	29,7	1281	70,3	302	23,6	1,37		Algorithm converged.	1,14	1,63	0,061		Algorithm converged.	0,026	0,095	1,258		Algorithm converged.	1,103	1,434	0,0006	0,6965	0,795		Algorithm converged.	0,698	0,906
		Non-anthracycline	307	17,0	84	27,4	316	17,3	73	23,1	1,25		Algorithm converged.	0,87	1,80	0,043		Algorithm converged.	-0,026	0,111	1,184		Algorithm converged.	0,903	1,554	0,2217		0,844		Algorithm converged.	0,644	1,108
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	749	41,4	205	27,4	754	41,4	190	25,2	1,12		Algorithm converged.	0,89	1,41	0,022		Algorithm converged.	-0,023	0,066	1,086		Algorithm converged.	0,917	1,287	0,3393	0,0306	0,921		Algorithm converged.	0,777	1,091
		Positive (ER and/or PgR positive)	789	43,6	244	30,9	843	46,2	185	21,9	1,59		Algorithm converged.	1,28	1,99	0,090		Algorithm converged.	0,047	0,132	1,409		Algorithm converged.	1,195	1,661	<.0001		0,710		Algorithm converged.	0,602	0,837

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	215	11,9	58	27,0	223	12,2	49	22,0	1,31		Algorithm converged.	0,85	2,03	0,050		Algorithm converged.	-0,030	0,130	1,228		Algorithm converged.	0,882	1,709	0,2244	0,6889	0,815		Algorithm converged.	0,585	1,134
		Western Europe	662	36,6	240	36,3	681	37,4	204	30,0	1,33		Algorithm converged.	1,06	1,67	0,063		Algorithm converged.	0,013	0,113	1,210		Algorithm converged.	1,039	1,410	0,0145		0,826		Algorithm converged.	0,709	0,963
		Asia Pacific	461	25,5	108	23,4	488	26,8	83	17,0	1,49		Algorithm converged.	1,08	2,06	0,064		Algorithm converged.	0,013	0,115	1,377		Algorithm converged.	1,066	1,780	0,0143		0,726		Algorithm converged.	0,562	0,938
		Latin America	38	2,1	11	28,9	42	2,3	7	16,7	2,04		Algorithm converged.	0,70	5,95	0,123		Algorithm converged.	-0,060	0,306	1,737		Algorithm converged.	0,750	4,023	0,1977		0,576		Algorithm converged.	0,249	1,334
		Other	162	8,9	32	19,8	163	8,9	32	19,6	1,01		Algorithm converged.	0,58	1,74	0,001		Algorithm converged.	-0,085	0,088	1,006		Algorithm converged.	0,649	1,561	0,9781		0,994		Algorithm converged.	0,641	1,542
	Protocol version	Protocol A	1050	58,0	306	29,1	1093	60,0	254	23,2	1,36		Algorithm converged.	1,12	1,65	0,059		Algorithm converged.	0,022	0,096	1,254		Algorithm converged.	1,087	1,447	0,0019	0,8334	0,797		Algorithm converged.	0,691	0,920
		Protocol amendment B	488	26,9	143	29,3	504	27,6	121	24,0	1,31		Algorithm converged.	0,99	1,74	0,053		Algorithm converged.	-0,002	0,108	1,221		Algorithm converged.	0,992	1,502	0,0599		0,819		Algorithm converged.	0,666	1,008
	Nodal status	0 positive nodes	268	14,8	90	33,6	283	15,5	80	28,3	1,28		Algorithm converged.	0,89	1,84	0,053		Algorithm converged.	-0,024	0,130	1,188		Algorithm converged.	0,925	1,526	0,1779	0,6882	0,842		Algorithm converged.	0,655	1,081
		>= 1 positive nodes	1270	70,1	359	28,3	1314	72,1	295	22,5	1,36		Algorithm converged.	1,14	1,63	0,058		Algorithm converged.	0,025	0,092	1,259		Algorithm converged.	1,102	1,439	0,0007		0,794		Algorithm converged.	0,695	0,907
	Menopausal status at randomization	Premenopausal	753	41,6	204	27,1	798	43,8	170	21,3	1,37		Algorithm converged.	1,09	1,73	0,058		Algorithm converged.	0,015	0,100	1,272		Algorithm converged.	1,065	1,519	0,0080	0,6935	0,786		Algorithm converged.	0,658	0,939
		Postmenopausal	781	43,1	243	31,1	791	43,4	203	25,7	1,31		Algorithm converged.	1,05	1,63	0,055		Algorithm converged.	0,010	0,099	1,212		Algorithm converged.	1,035	1,420	0,0169		0,825		Algorithm converged.	0,704	0,966
		Unknown/Missing	4	0,2	2	50,0	8	0,4	2	25,0	3,00		Algorithm converged.	0,24	37,67	0,250		Algorithm converged.	-0,325	0,825	2,000		Algorithm converged.	0,425	9,418	0,3806		0,500		Algorithm converged.	0,106	2,355
	Age II	< 65	1358	75,0	374	27,5	1422	78,0	327	23,0	1,27		Algorithm converged.	1,07	1,51	0,045		Algorithm converged.	0,013	0,078	1,198		Algorithm converged.	1,053	1,362	0,0059	0,1447	0,835		Algorithm converged.	0,734	0,949
		>= 65	180	9,9	75	41,7	175	9,6	48	27,4	1,89		Algorithm converged.	1,21	2,95	0,142		Algorithm converged.	0,045	0,240	1,519		Algorithm converged.	1,129	2,044	0,0057		0,658		Algorithm converged.	0,489	0,886

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	10	37,0	22	1,2	6	27,3	1,57		Algorithm converged.	0,46	5,32	0,098		Algorithm converged.	-0,163	0,358	1,358		Algorithm converged.	0,586	3,149	0,4758	0,9571	0,736		Algorithm converged.	0,318	1,708
		Grade 2	472	26,1	126	26,7	487	26,7	108	22,2	1,28		Algorithm converged.	0,95	1,72	0,045		Algorithm converged.	-0,009	0,100	1,204		Algorithm converged.	0,962	1,505	0,1042		0,831		Algorithm converged.	0,664	1,039
		Grade 3	980	54,1	298	30,4	1029	56,4	254	24,7	1,33		Algorithm converged.	1,10	1,62	0,057		Algorithm converged.	0,018	0,096	1,232		Algorithm converged.	1,068	1,421	0,0042		0,812		Algorithm converged.	0,704	0,936
		Unevaluable/Unknown/Missing	59	3,3	15	25,4	59	3,2	7	11,9	2,53		Algorithm converged.	0,95	6,77	0,136		Algorithm converged.	-0,003	0,274	2,143		Algorithm converged.	0,942	4,872	0,0690		0,467		Algorithm converged.	0,205	1,061
	Type of surgery for primary tumor	Breast conserving surgery	608	33,6	212	34,9	602	33,0	163	27,1	1,44		Algorithm converged.	1,13	1,84	0,078		Algorithm converged.	0,026	0,130	1,288		Algorithm converged.	1,086	1,527	0,0036	0,5589	0,777		Algorithm converged.	0,655	0,921
		Mastectomy	930	51,4	237	25,5	994	54,5	211	21,2	1,27		Algorithm converged.	1,03	1,57	0,043		Algorithm converged.	0,005	0,080	1,201		Algorithm converged.	1,020	1,412	0,0275		0,833		Algorithm converged.	0,708	0,980
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	566	31,3	180	31,8	581	31,9	143	24,6	1,43		Algorithm converged.	1,10	1,85	0,072		Algorithm converged.	0,020	0,124	1,292		Algorithm converged.	1,072	1,557	0,0071	0,6083	0,774		Algorithm converged.	0,642	0,933
		>= 2 - < 5 cm	847	46,8	229	27,0	864	47,4	197	22,8	1,25		Algorithm converged.	1,01	1,56	0,042		Algorithm converged.	0,001	0,083	1,186		Algorithm converged.	1,005	1,399	0,0432		0,843		Algorithm converged.	0,715	0,995
		>= 5 cm	123	6,8	40	32,5	150	8,2	34	22,7	1,64		Algorithm converged.	0,96	2,81	0,099		Algorithm converged.	-0,008	0,205	1,435		Algorithm converged.	0,971	2,119	0,0697		0,697		Algorithm converged.	0,472	1,030
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1190	65,7	370	31,1	1207	66,2	285	23,6	1,46		Algorithm converged.	1,22	1,75	0,075		Algorithm converged.	0,039	0,110	1,317		Algorithm converged.	1,154	1,503	<.0001	0,0534	0,759		Algorithm converged.	0,665	0,867
		No	348	19,2	79	22,7	390	21,4	90	23,1	0,98		Algorithm converged.	0,69	1,38	-0,004		Algorithm converged.	-0,064	0,057	0,984		Algorithm converged.	0,754	1,283	0,9035		1,017		Algorithm converged.	0,780	1,325
	Race	White	1017	56,2	324	31,9	1062	58,3	282	26,6	1,29		Algorithm converged.	1,07	1,56	0,053		Algorithm converged.	0,014	0,092	1,200		Algorithm converged.	1,049	1,372	0,0079	0,7535	0,833		Algorithm converged.	0,729	0,953
		Black	21	1,2	8	38,1	27	1,5	7	25,9	1,76		Algorithm converged.	0,51	6,02	0,122		Algorithm converged.	-0,144	0,387	1,469		Algorithm converged.	0,635	3,400	0,3686		0,681		Algorithm converged.	0,294	1,575
		Asian	449	24,8	103	22,9	460	25,2	76	16,5	1,50		Algorithm converged.	1,08	2,09	0,064		Algorithm converged.	0,013	0,116	1,388		Algorithm converged.	1,064	1,812	0,0157		0,720		Algorithm converged.	0,552	0,940
		Other	47	2,6	14	29,8	47	2,6	10	21,3	1,57		Algorithm converged.	0,61	4,01	0,085		Algorithm converged.	-0,090	0,261	1,400		Algorithm converged.	0,693	2,829	0,3486		0,714		Algorithm converged.	0,353	1,444
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1361	75,2	245	18,0	1327	72,8	271	20,4	0,86		Algorithm converged.	0,71	1,04	-0,024		Algorithm converged.	-0,054	0,006	0,881		Algorithm converged.	0,755	1,030	0,1115		1,134		Algorithm converged.	0,971	1,325
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	9	20,5	35	1,9	6	17,1	1,24		Algorithm converged.	0,40	3,90	0,033		Algorithm converged.	-0,139	0,206	1,193		Algorithm converged.	0,469	3,032	0,7105	0,4222	0,838		Algorithm converged.	0,330	2,130
		0 positive nodes, tumor > 1 cm	213	11,8	45	21,1	222	12,2	43	19,4	1,12		Algorithm converged.	0,70	1,78	0,018		Algorithm converged.	-0,058	0,093	1,091		Algorithm converged.	0,751	1,584	0,6484		0,917		Algorithm converged.	0,631	1,332
		1-3 positive nodes	692	38,2	125	18,1	656	36,0	134	20,4	0,86		Algorithm converged.	0,65	1,13	-0,024		Algorithm converged.	-0,066	0,018	0,884		Algorithm converged.	0,710	1,101	0,2713		1,131		Algorithm converged.	0,908	1,408
		>= 4 positive nodes	412	22,7	66	16,0	414	22,7	88	21,3	0,71		Algorithm converged.	0,50	1,01	-0,052		Algorithm converged.	-0,105	0,001	0,754		Algorithm converged.	0,565	1,006	0,0547		1,327		Algorithm converged.	0,994	1,771
	Adjuvant chemotherapy regimen	Anthracycline	1086	60,0	199	18,3	1067	58,5	219	20,5	0,87		Algorithm converged.	0,70	1,08	-0,022		Algorithm converged.	-0,055	0,011	0,893		Algorithm converged.	0,751	1,061	0,1971	0,7477	1,120		Algorithm converged.	0,943	1,331

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	275	15,2	46	16,7	260	14,3	52	20,0	0,80		Algorithm converged.	0,52	1,25	-0,033		Algorithm converged.	-0,098	0,033	0,836		Algorithm converged.	0,584	1,197	0,3288		1,196		Algorithm converged.	0,835	1,711
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	115	17,3	644	35,3	118	18,3	0,93		Algorithm converged.	0,70	1,24	-0,010		Algorithm converged.	-0,052	0,031	0,944		Algorithm converged.	0,748	1,191	0,6264	0,4371	1,060		Algorithm converged.	0,839	1,337
		Positive (ER and/or PgR positive)	696	38,4	130	18,7	683	37,5	153	22,4	0,80		Algorithm converged.	0,61	1,03	-0,037		Algorithm converged.	-0,080	0,005	0,834		Algorithm converged.	0,677	1,027	0,0877		1,199		Algorithm converged.	0,974	1,478
	Geographical region II	USA/Canada	179	9,9	31	17,3	154	8,4	25	16,2	1,08		Algorithm converged.	0,61	1,93	0,011		Algorithm converged.	-0,070	0,091	1,067		Algorithm converged.	0,660	1,725	0,7920	-	0,937		Algorithm converged.	0,580	1,516
		Western Europe	586	32,4	137	23,4	578	31,7	150	26,0	0,87		Algorithm converged.	0,67	1,14	-0,026		Algorithm converged.	-0,075	0,024	0,901		Algorithm converged.	0,737	1,102	0,3090		1,110		Algorithm converged.	0,908	1,357
		Asia Pacific	415	22,9	55	13,3	428	23,5	65	15,2	0,85		Algorithm converged.	0,58	1,26	-0,019		Algorithm converged.	-0,066	0,028	0,873		Algorithm converged.	0,626	1,217	0,4224		1,146		Algorithm converged.	0,822	1,598
		Latin America	34	1,9	2	5,9	36	2,0	7	19,4	0,26		Algorithm converged.	0,05	1,35	-0,136		Algorithm converged.	-0,287	0,016	0,303		Algorithm converged.	0,068	1,356	0,1182		3,306		Algorithm converged.	0,738	14,814
		Other	147	8,1	20	13,6	131	7,2	24	18,3	0,70		Algorithm converged.	0,37	1,34	-0,047		Algorithm converged.	-0,134	0,039	0,743		Algorithm converged.	0,431	1,280	0,2843		1,347		Algorithm converged.	0,781	2,322
	Protocol version	Protocol A	956	52,8	176	18,4	918	50,4	186	20,3	0,89		Algorithm converged.	0,71	1,12	-0,019		Algorithm converged.	-0,054	0,017	0,909		Algorithm converged.	0,755	1,093	0,3104	0,5538	1,101		Algorithm converged.	0,915	1,324
		Protocol amendment B	405	22,4	69	17,0	409	22,4	85	20,8	0,78		Algorithm converged.	0,55	1,11	-0,037		Algorithm converged.	-0,091	0,016	0,820		Algorithm converged.	0,616	1,092	0,1738		1,220		Algorithm converged.	0,916	1,624
	Nodal status	0 positive nodes	257	14,2	54	21,0	257	14,1	49	19,1	1,13		Algorithm converged.	0,73	1,74	0,019		Algorithm converged.	-0,050	0,089	1,102		Algorithm converged.	0,780	1,557	0,5819	0,1578	0,907		Algorithm converged.	0,642	1,282
		>= 1 positive nodes	1104	61,0	191	17,3	1070	58,7	222	20,7	0,80		Algorithm converged.	0,64	0,99	-0,034		Algorithm converged.	-0,067	-0,001	0,834		Algorithm converged.	0,701	0,993	0,0409		1,199		Algorithm converged.	1,008	1,427
	Menopausal status at randomization	Premenopausal	662	36,6	113	17,1	659	36,1	129	19,6	0,85		Algorithm converged.	0,64	1,12	-0,025		Algorithm converged.	-0,067	0,017	0,872		Algorithm converged.	0,694	1,096	0,2397	0,9614	1,147		Algorithm converged.	0,913	1,441

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	695	38,4	131	18,8	662	36,3	142	21,5	0,85		Algorithm converged.	0,65	1,11	-0,026		Algorithm converged.	-0,069	0,017	0,879		Algorithm converged.	0,711	1,087	0,2326		1,138		Algorithm converged.	0,920	1,407
		Unknown/Missing	4	0,2	1	25,0	6	0,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Age II	< 65	1208	66,7	210	17,4	1185	65,0	238	20,1	0,84		Algorithm converged.	0,68	1,03	-0,027		Algorithm converged.	-0,058	0,004	0,866		Algorithm converged.	0,732	1,023	0,0909	0,5748	1,155		Algorithm converged.	0,977	1,366
		>= 65	153	8,4	35	22,9	142	7,8	33	23,2	0,98		Algorithm converged.	0,57	1,68	-0,004		Algorithm converged.	-0,100	0,093	0,984		Algorithm converged.	0,649	1,494	0,9409		1,016		Algorithm converged.	0,669	1,542
	Histological grade	Grade 1	26	1,4	8	30,8	20	1,1	6	30,0	1,04		Algorithm converged.	0,29	3,69	0,008		Algorithm converged.	-0,260	0,276	1,026		Algorithm converged.	0,424	2,481	0,9552	0,9461	0,975		Algorithm converged.	0,403	2,359
		Grade 2	427	23,6	70	16,4	407	22,3	76	18,7	0,85		Algorithm converged.	0,60	1,22	-0,023		Algorithm converged.	-0,074	0,029	0,878		Algorithm converged.	0,654	1,179	0,3869		1,139		Algorithm converged.	0,848	1,530
		Grade 3	859	47,4	161	18,7	849	46,6	180	21,2	0,86		Algorithm converged.	0,68	1,09	-0,025		Algorithm converged.	-0,062	0,013	0,884		Algorithm converged.	0,731	1,069	0,2042		1,131		Algorithm converged.	0,935	1,368
		Unevaluable/Unknown/Missing	49	2,7	6	12,2	51	2,8	9	17,6	0,65		Algorithm converged.	0,21	1,99	-0,054		Algorithm converged.	-0,193	0,085	0,694		Algorithm converged.	0,267	1,804	0,4536		1,441		Algorithm converged.	0,554	3,748
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	116	21,2	520	28,5	116	22,3	0,94		Algorithm converged.	0,70	1,25	-0,011		Algorithm converged.	-0,061	0,039	0,951		Algorithm converged.	0,757	1,194	0,6630	0,3723	1,052		Algorithm converged.	0,838	1,321
		Mastectomy	814	44,9	129	15,8	807	44,3	155	19,2	0,79		Algorithm converged.	0,61	1,02	-0,034		Algorithm converged.	-0,071	0,003	0,825		Algorithm converged.	0,667	1,020	0,0760		1,212		Algorithm converged.	0,980	1,499

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Tumor size	0 - < 2 cm	514	28,4	90	17,5	490	26,9	103	21,0	0,80		Algorithm converged.	0,58	1,09	-0,035		Algorithm converged.	-0,084	0,014	0,833		Algorithm converged.	0,646	1,074	0,1590	0,6660	1,200		Algorithm converged.	0,931	1,548
		>= 2 - < 5 cm	745	41,1	140	18,8	721	39,6	145	20,1	0,92		Algorithm converged.	0,71	1,19	-0,013		Algorithm converged.	-0,054	0,027	0,934		Algorithm converged.	0,759	1,151	0,5236		1,070		Algorithm converged.	0,869	1,318
		>= 5 cm	100	5,5	15	15,0	114	6,3	23	20,2	0,70		Algorithm converged.	0,34	1,43	-0,052		Algorithm converged.	-0,153	0,050	0,743		Algorithm converged.	0,411	1,345	0,3268		1,345		Algorithm converged.	0,744	2,432
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1041	57,5	199	19,1	1012	55,5	219	21,6	0,86		Algorithm converged.	0,69	1,06	-0,025		Algorithm converged.	-0,060	0,010	0,883		Algorithm converged.	0,744	1,048	0,1560	0,9445	1,132		Algorithm converged.	0,954	1,344
		No	320	17,7	46	14,4	315	17,3	52	16,5	0,85		Algorithm converged.	0,55	1,31	-0,021		Algorithm converged.	-0,078	0,035	0,871		Algorithm converged.	0,605	1,254	0,4575		1,148		Algorithm converged.	0,797	1,654
	Race	White	895	49,4	183	20,4	879	48,2	192	21,8	0,92		Algorithm converged.	0,73	1,16	-0,014		Algorithm converged.	-0,052	0,024	0,936		Algorithm converged.	0,782	1,121	0,4716	0,0328	1,068		Algorithm converged.	0,892	1,279
		Black	18	1,0	1	5,6	19	1,0	9	47,4	0,07		Algorithm converged.	0,01	0,60	-0,418		Algorithm converged.	-0,666	-0,170	0,117		Algorithm converged.	0,016	0,835	0,0324		8,526		Algorithm converged.	1,198	60,702
		Asian	399	22,0	54	13,5	395	21,7	63	15,9	0,82		Algorithm converged.	0,56	1,22	-0,024		Algorithm converged.	-0,073	0,025	0,849		Algorithm converged.	0,607	1,187	0,3378		1,178		Algorithm converged.	0,842	1,649
		Other	44	2,4	6	13,6	33	1,8	7	21,2	0,59		Algorithm converged.	0,18	1,95	-0,076		Algorithm converged.	-0,248	0,097	0,643		Algorithm converged.	0,238	1,735	0,3830		1,556		Algorithm converged.	0,576	4,197
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC01_W15_SG.xls
26OCT2020 16:00

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1542	85,1	184	11,9	1598	87,7	176	11,0	1,09		Algorithm converged.	0,88	1,36	0,009		Algorithm converged.	-0,013	0,031	1,083		Algorithm converged.	0,892	1,316	0,4193		0,923		Algorithm converged.	0,760	1,121
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	6	14,0	35	1,9	4	11,4	1,26		Algorithm converged.	0,33	4,86	0,025		Algorithm converged.	-0,123	0,173	1,221		Algorithm converged.	0,374	3,989	0,7410	0,3525	0,819		Algorithm converged.	0,251	2,676
		0 positive nodes, tumor > 1 cm	225	12,4	22	9,8	248	13,6	34	13,7	0,68		Algorithm converged.	0,39	1,21	-0,039		Algorithm converged.	-0,097	0,018	0,713		Algorithm converged.	0,430	1,182	0,1896		1,402		Algorithm converged.	0,846	2,323
		1-3 positive nodes	771	42,6	98	12,7	797	43,7	85	10,7	1,22		Algorithm converged.	0,90	1,66	0,020		Algorithm converged.	-0,011	0,052	1,192		Algorithm converged.	0,907	1,566	0,2079		0,839		Algorithm converged.	0,639	1,103
		>= 4 positive nodes	503	27,8	58	11,5	518	28,4	53	10,2	1,14		Algorithm converged.	0,77	1,70	0,013		Algorithm converged.	-0,025	0,051	1,127		Algorithm converged.	0,793	1,602	0,5053		0,887		Algorithm converged.	0,624	1,261
	Adjuvant chemotherapy regimen	Anthracycline	1234	68,1	133	10,8	1281	70,3	135	10,5	1,03		Algorithm converged.	0,80	1,32	0,002		Algorithm converged.	-0,022	0,027	1,023		Algorithm converged.	0,816	1,282	0,8458	0,3185	0,978		Algorithm converged.	0,780	1,226
		Non-anthracycline	308	17,0	51	16,6	317	17,4	41	12,9	1,34		Algorithm converged.	0,86	2,08	0,036		Algorithm converged.	-0,019	0,092	1,280		Algorithm converged.	0,875	1,872	0,2026		0,781		Algorithm converged.	0,534	1,142
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	751	41,5	79	10,5	754	41,4	86	11,4	0,91		Algorithm converged.	0,66	1,26	-0,009		Algorithm converged.	-0,040	0,023	0,922		Algorithm converged.	0,691	1,230	0,5822	0,1324	1,084		Algorithm converged.	0,813	1,447
		Positive (ER and/or PgR positive)	791	43,7	105	13,3	844	46,3	90	10,7	1,28		Algorithm converged.	0,95	1,73	0,026		Algorithm converged.	-0,005	0,058	1,245		Algorithm converged.	0,956	1,621	0,1044		0,803		Algorithm converged.	0,617	1,046

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	215	11,9	35	16,3	224	12,3	29	12,9	1,31		Algorithm converged.	0,77	2,23	0,033		Algorithm converged.	-0,033	0,099	1,257		Algorithm converged.	0,798	1,982	0,3240	-	0,795		Algorithm converged.	0,504	1,254
		Western Europe	666	36,8	94	14,1	681	37,4	80	11,7	1,23		Algorithm converged.	0,90	1,70	0,024		Algorithm converged.	-0,012	0,059	1,201		Algorithm converged.	0,910	1,587	0,1962		0,832		Algorithm converged.	0,630	1,099
		Asia Pacific	461	25,5	40	8,7	488	26,8	40	8,2	1,06		Algorithm converged.	0,67	1,68	0,005		Algorithm converged.	-0,031	0,040	1,059		Algorithm converged.	0,696	1,610	0,7902		0,945		Algorithm converged.	0,621	1,437
		Latin America	38	2,1	2	5,3	42	2,3	6	14,3	0,33		Algorithm converged.	0,06	1,76	-0,090		Algorithm converged.	-0,218	0,037	0,368		Algorithm converged.	0,079	1,717	0,2035		2,714		Algorithm converged.	0,582	12,648
		Other	162	8,9	13	8,0	163	8,9	21	12,9	0,59		Algorithm converged.	0,28	1,22	-0,049		Algorithm converged.	-0,115	0,018	0,623		Algorithm converged.	0,323	1,201	0,1576		1,605		Algorithm converged.	0,833	3,096
	Protocol version	Protocol A	1052	58,1	122	11,6	1093	60,0	126	11,5	1,01		Algorithm converged.	0,77	1,31	0,001		Algorithm converged.	-0,026	0,028	1,006		Algorithm converged.	0,796	1,271	0,9601	0,2655	0,994		Algorithm converged.	0,787	1,256
		Protocol amendment B	490	27,1	62	12,7	505	27,7	50	9,9	1,32		Algorithm converged.	0,89	1,96	0,028		Algorithm converged.	-0,012	0,067	1,278		Algorithm converged.	0,899	1,816	0,1711		0,782		Algorithm converged.	0,551	1,112
	Nodal status	0 positive nodes	268	14,8	28	10,4	283	15,5	38	13,4	0,75		Algorithm converged.	0,45	1,26	-0,030		Algorithm converged.	-0,084	0,024	0,778		Algorithm converged.	0,492	1,231	0,2836	0,1149	1,285		Algorithm converged.	0,812	2,033
		>= 1 positive nodes	1274	70,3	156	12,2	1315	72,1	138	10,5	1,19		Algorithm converged.	0,93	1,52	0,018		Algorithm converged.	-0,007	0,042	1,167		Algorithm converged.	0,940	1,448	0,1610		0,857		Algorithm converged.	0,691	1,063
	Menopausal status at randomization	Premenopausal	754	41,6	93	12,3	799	43,8	78	9,8	1,30		Algorithm converged.	0,95	1,79	0,026		Algorithm converged.	-0,005	0,057	1,263		Algorithm converged.	0,951	1,678	0,1065	0,1194	0,791		Algorithm converged.	0,596	1,051
		Postmenopausal	784	43,3	90	11,5	791	43,4	98	12,4	0,92		Algorithm converged.	0,68	1,24	-0,009		Algorithm converged.	-0,041	0,023	0,927		Algorithm converged.	0,708	1,212	0,5778		1,079		Algorithm converged.	0,825	1,412

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	1	25,0	8	0,4	0	0,0	NE		Algorithm converged.	NE	NE	0,262	*	WARNING: The relative Hessian convergence criterion of 3.5555052554 is greater than the limit of 0.0001. The convergence is questionable.	-0,557	1,082	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Age II	< 65	1361	75,2	151	11,1	1423	78,1	161	11,3	0,98		Algorithm converged.	0,77	1,24	-0,002		Algorithm converged.	-0,026	0,021	0,981		Algorithm converged.	0,795	1,209	0,8545	0,0099	1,020		Algorithm converged.	0,827	1,257
		>= 65	181	10,0	33	18,2	175	9,6	15	8,6	2,38		Algorithm converged.	1,24	4,56	0,097		Algorithm converged.	0,027	0,166	2,127		Algorithm converged.	1,198	3,776	0,0099		0,470		Algorithm converged.	0,265	0,835
	Histological grade	Grade 1	27	1,5	2	7,4	22	1,2	4	18,2	0,36		Algorithm converged.	0,06	2,18	-0,108		Algorithm converged.	-0,297	0,081	0,407		Algorithm converged.	0,082	2,021	0,2717	-	2,455		Algorithm converged.	0,495	12,173
		Grade 2	473	26,1	57	12,1	487	26,7	60	12,3	0,98		Algorithm converged.	0,66	1,44	-0,003		Algorithm converged.	-0,044	0,039	0,978		Algorithm converged.	0,696	1,374	0,8984		1,022		Algorithm converged.	0,728	1,436
		Grade 3	983	54,3	123	12,5	1030	56,5	107	10,4	1,23		Algorithm converged.	0,94	1,62	0,021		Algorithm converged.	-0,007	0,049	1,204		Algorithm converged.	0,944	1,537	0,1349		0,830		Algorithm converged.	0,651	1,060
		Unevaluable/Unknown/Missing	59	3,3	2	3,4	59	3,2	5	8,5	0,38		Algorithm converged.	0,07	2,04	-0,051		Algorithm converged.	-0,136	0,034	0,400		Algorithm converged.	0,081	1,980	0,2616		2,500		Algorithm converged.	0,505	12,378
	Type of surgery for primary tumor	Breast conserving surgery	609	33,6	76	12,5	602	33,0	62	10,3	1,24		Algorithm converged.	0,87	1,77	0,022		Algorithm converged.	-0,014	0,058	1,212		Algorithm converged.	0,883	1,662	0,2335	0,3741	0,825		Algorithm converged.	0,602	1,132

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Mastectomy	933	51,5	108	11,6	995	54,6	114	11,5	1,01		Algorithm converged.	0,76	1,34	0,001		Algorithm converged.	-0,027	0,030	1,010		Algorithm converged.	0,789	1,294	0,9352		0,990		Algorithm converged.	0,773	1,268
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	569	31,4	69	12,1	582	31,9	53	9,1	1,38		Algorithm converged.	0,94	2,01	0,030		Algorithm converged.	-0,005	0,066	1,332		Algorithm converged.	0,949	1,869	0,0976	0,2953	0,751		Algorithm converged.	0,535	1,054
		>= 2 - < 5 cm	848	46,8	97	11,4	864	47,4	97	11,2	1,02		Algorithm converged.	0,76	1,38	0,002		Algorithm converged.	-0,028	0,032	1,019		Algorithm converged.	0,782	1,328	0,8900		0,981		Algorithm converged.	0,753	1,279
		>= 5 cm	123	6,8	18	14,6	150	8,2	26	17,3	0,82		Algorithm converged.	0,42	1,57	-0,027		Algorithm converged.	-0,114	0,060	0,844		Algorithm converged.	0,486	1,466	0,5476		1,184		Algorithm converged.	0,682	2,056
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1192	65,8	145	12,2	1208	66,3	126	10,4	1,19		Algorithm converged.	0,92	1,53	0,017		Algorithm converged.	-0,008	0,043	1,166		Algorithm converged.	0,931	1,460	0,1802	0,2016	0,857		Algorithm converged.	0,685	1,074
		No	350	19,3	39	11,1	390	21,4	50	12,8	0,85		Algorithm converged.	0,55	1,33	-0,017		Algorithm converged.	-0,064	0,030	0,869		Algorithm converged.	0,587	1,288	0,4844		1,151		Algorithm converged.	0,777	1,705
	Race	White	1020	56,3	137	13,4	1063	58,3	132	12,4	1,09		Algorithm converged.	0,85	1,41	0,010		Algorithm converged.	-0,019	0,039	1,082		Algorithm converged.	0,865	1,352	0,4905	-	0,925		Algorithm converged.	0,740	1,156
		Black	21	1,2	6	28,6	27	1,5	3	11,1	3,20		Algorithm converged.	0,69	14,76	0,175		Algorithm converged.	-0,052	0,401	2,571		Algorithm converged.	0,727	9,094	0,1428		0,389		Algorithm converged.	0,110	1,375
		Asian	450	24,8	37	8,2	460	25,2	35	7,6	1,09		Algorithm converged.	0,67	1,76	0,006		Algorithm converged.	-0,029	0,041	1,081		Algorithm converged.	0,694	1,684	0,7318		0,925		Algorithm converged.	0,594	1,442
		Other	47	2,6	3	6,4	47	2,6	6	12,8	0,47		Algorithm converged.	0,11	1,99	-0,064		Algorithm converged.	-0,182	0,054	0,500		Algorithm converged.	0,133	1,882	0,3054		2,000		Algorithm converged.	0,531	7,529

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1363	75,3	125	9,2	1328	72,8	132	9,9	0,91		Algorithm converged.	0,71	1,18	-0,008		Algorithm converged.	-0,030	0,015	0,923		Algorithm converged.	0,731	1,164	0,4976		1,084		Algorithm converged.	0,859	1,368
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	4	9,1	35	1,9	3	8,6	1,07		Algorithm converged.	0,22	5,11	0,005		Algorithm converged.	-0,121	0,131	1,061		Algorithm converged.	0,254	4,430	0,9357	-	0,943		Algorithm converged.	0,226	3,938
		0 positive nodes, tumor > 1 cm	213	11,8	13	6,1	222	12,2	22	9,9	0,59		Algorithm converged.	0,29	1,21	-0,038		Algorithm converged.	-0,089	0,013	0,616		Algorithm converged.	0,319	1,191	0,1496		1,624		Algorithm converged.	0,840	3,140
		1-3 positive nodes	694	38,3	66	9,5	657	36,0	63	9,6	0,99		Algorithm converged.	0,69	1,42	-0,001		Algorithm converged.	-0,032	0,031	0,992		Algorithm converged.	0,714	1,377	0,9606		1,008		Algorithm converged.	0,726	1,400
		>= 4 positive nodes	412	22,7	42	10,2	414	22,7	44	10,6	0,95		Algorithm converged.	0,61	1,49	-0,004		Algorithm converged.	-0,046	0,037	0,959		Algorithm converged.	0,643	1,431	0,8383		1,043		Algorithm converged.	0,699	1,556
	Adjuvant chemotherapy regimen	Anthracycline	1088	60,1	91	8,4	1067	58,5	101	9,5	0,87		Algorithm converged.	0,65	1,17	-0,011		Algorithm converged.	-0,035	0,013	0,884		Algorithm converged.	0,674	1,158	0,3697	0,5446	1,132		Algorithm converged.	0,864	1,483
		Non-anthracycline	275	15,2	34	12,4	261	14,3	31	11,9	1,05		Algorithm converged.	0,62	1,76	0,005		Algorithm converged.	-0,050	0,060	1,041		Algorithm converged.	0,660	1,643	0,8632		0,961		Algorithm converged.	0,609	1,516
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	54	8,1	644	35,3	59	9,2	0,88		Algorithm converged.	0,60	1,29	-0,010		Algorithm converged.	-0,041	0,020	0,886		Algorithm converged.	0,623	1,261	0,5028	0,7616	1,128		Algorithm converged.	0,793	1,606

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	698	38,5	71	10,2	684	37,5	73	10,7	0,95		Algorithm converged.	0,67	1,34	-0,005		Algorithm converged.	-0,037	0,027	0,953		Algorithm converged.	0,700	1,298	0,7607		1,049		Algorithm converged.	0,770	1,429
	Geographical region II	USA/Canada	179	9,9	23	12,8	155	8,5	16	10,3	1,28		Algorithm converged.	0,65	2,52	0,025		Algorithm converged.	-0,043	0,094	1,245		Algorithm converged.	0,683	2,270	0,4750	-	0,803		Algorithm converged.	0,441	1,465
		Western Europe	588	32,5	62	10,5	578	31,7	56	9,7	1,10		Algorithm converged.	0,75	1,61	0,009		Algorithm converged.	-0,026	0,043	1,088		Algorithm converged.	0,773	1,533	0,6283		0,919		Algorithm converged.	0,652	1,294
		Asia Pacific	415	22,9	27	6,5	428	23,5	36	8,4	0,76		Algorithm converged.	0,45	1,27	-0,019		Algorithm converged.	-0,054	0,016	0,773		Algorithm converged.	0,478	1,250	0,2947		1,293		Algorithm converged.	0,800	2,090
		Latin America	34	1,9	3	8,8	36	2,0	5	13,9	0,60		Algorithm converged.	0,13	2,73	-0,051		Algorithm converged.	-0,198	0,097	0,635		Algorithm converged.	0,164	2,457	0,5109		1,574		Algorithm converged.	0,407	6,087
		Other	147	8,1	10	6,8	131	7,2	19	14,5	0,43		Algorithm converged.	0,19	0,96	-0,077		Algorithm converged.	-0,150	-0,004	0,469		Algorithm converged.	0,226	0,972	0,0417		2,132		Algorithm converged.	1,029	4,418
	Protocol version	Protocol A	958	52,9	86	9,0	918	50,4	93	10,1	0,87		Algorithm converged.	0,64	1,19	-0,012		Algorithm converged.	-0,038	0,015	0,886		Algorithm converged.	0,670	1,171	0,3955	0,6059	1,129		Algorithm converged.	0,854	1,492
		Protocol amendment B	405	22,4	39	9,6	410	22,5	39	9,5	1,01		Algorithm converged.	0,64	1,62	0,001		Algorithm converged.	-0,039	0,042	1,012		Algorithm converged.	0,664	1,544	0,9546		0,988		Algorithm converged.	0,648	1,507
	Nodal status	0 positive nodes	257	14,2	17	6,6	257	14,1	25	9,7	0,66		Algorithm converged.	0,35	1,25	-0,031		Algorithm converged.	-0,078	0,016	0,680		Algorithm converged.	0,376	1,228	0,2012	0,2655	1,471		Algorithm converged.	0,814	2,657
		>= 1 positive nodes	1106	61,1	108	9,8	1071	58,7	107	10,0	0,97		Algorithm converged.	0,74	1,29	-0,002		Algorithm converged.	-0,027	0,023	0,977		Algorithm converged.	0,758	1,260	0,8599		1,023		Algorithm converged.	0,794	1,319
	Menopausal status at randomization	Premenopausal	663	36,6	63	9,5	660	36,2	71	10,8	0,87		Algorithm converged.	0,61	1,25	-0,013		Algorithm converged.	-0,045	0,020	0,883		Algorithm converged.	0,640	1,218	0,4496	0,6540	1,132		Algorithm converged.	0,821	1,562
		Postmenopausal	696	38,4	62	8,9	662	36,3	60	9,1	0,98		Algorithm converged.	0,68	1,42	-0,002		Algorithm converged.	-0,032	0,029	0,983		Algorithm converged.	0,701	1,379	0,9203		1,017		Algorithm converged.	0,725	1,427

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	6	0,3	1	16,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1210	66,8	106	8,8	1186	65,1	119	10,0	0,86		Algorithm converged.	0,65	1,13	-0,013		Algorithm converged.	-0,036	0,011	0,873		Algorithm converged.	0,680	1,120	0,2858	0,2211	1,145		Algorithm converged.	0,893	1,470
		>= 65	153	8,4	19	12,4	142	7,8	13	9,2	1,41		Algorithm converged.	0,67	2,97	0,033		Algorithm converged.	-0,038	0,103	1,356		Algorithm converged.	0,696	2,644	0,3707		0,737		Algorithm converged.	0,378	1,437
	Histological grade	Grade 1	26	1,4	3	11,5	20	1,1	7	35,0	0,24		Algorithm converged.	0,05	1,10	-0,235		Algorithm converged.	-0,477	0,008	0,330		Algorithm converged.	0,097	1,117	0,0747	0,0641	3,033		Algorithm converged.	0,895	10,279
		Grade 2	428	23,6	31	7,2	407	22,3	39	9,6	0,74		Algorithm converged.	0,45	1,21	-0,023		Algorithm converged.	-0,061	0,014	0,756		Algorithm converged.	0,481	1,187	0,2245		1,323		Algorithm converged.	0,842	2,078
		Grade 3	860	47,5	90	10,5	850	46,6	80	9,4	1,12		Algorithm converged.	0,82	1,55	0,011		Algorithm converged.	-0,018	0,039	1,112		Algorithm converged.	0,835	1,480	0,4670		0,899		Algorithm converged.	0,676	1,197
		Unevaluable/Unknown/Missing	49	2,7	1	2,0	51	2,8	6	11,8	0,16		Algorithm converged.	0,02	1,35	-0,097		Algorithm converged.	-0,194	0,000	0,173		Algorithm converged.	0,022	1,389	0,0989		5,765		Algorithm converged.	0,720	46,161
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	45	8,2	520	28,5	50	9,6	0,84		Algorithm converged.	0,55	1,28	-0,014		Algorithm converged.	-0,048	0,020	0,856		Algorithm converged.	0,583	1,257	0,4265	0,6220	1,169		Algorithm converged.	0,796	1,717
		Mastectomy	816	45,1	80	9,8	808	44,3	82	10,1	0,96		Algorithm converged.	0,70	1,33	-0,003		Algorithm converged.	-0,033	0,026	0,966		Algorithm converged.	0,721	1,294	0,8168		1,035		Algorithm converged.	0,773	1,387
	Tumor size	0 - < 2 cm	516	28,5	40	7,8	491	26,9	50	10,2	0,74		Algorithm converged.	0,48	1,15	-0,024		Algorithm converged.	-0,060	0,011	0,761		Algorithm converged.	0,512	1,132	0,1780	0,3886	1,314		Algorithm converged.	0,883	1,954

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	745	41,1	76	10,2	721	39,6	69	9,6	1,07		Algorithm converged.	0,76	1,51	0,006		Algorithm converged.	-0,024	0,037	1,066		Algorithm converged.	0,782	1,453	0,6857		0,938		Algorithm converged.	0,688	1,278
		>= 5 cm	100	5,5	9	9,0	114	6,3	13	11,4	0,77		Algorithm converged.	0,31	1,88	-0,024		Algorithm converged.	-0,105	0,057	0,789		Algorithm converged.	0,352	1,768	0,5651		1,267		Algorithm converged.	0,566	2,838
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1042	57,5	95	9,1	1013	55,6	105	10,4	0,87		Algorithm converged.	0,65	1,16	-0,012		Algorithm converged.	-0,038	0,013	0,880		Algorithm converged.	0,676	1,145	0,3403	0,4533	1,137		Algorithm converged.	0,873	1,480
		No	321	17,7	30	9,3	315	17,3	27	8,6	1,10		Algorithm converged.	0,64	1,90	0,008		Algorithm converged.	-0,037	0,052	1,090		Algorithm converged.	0,664	1,791	0,7326		0,917		Algorithm converged.	0,558	1,506
	Race	White	896	49,5	88	9,8	880	48,3	94	10,7	0,91		Algorithm converged.	0,67	1,24	-0,009		Algorithm converged.	-0,037	0,020	0,919		Algorithm converged.	0,698	1,211	0,5501	-	1,088		Algorithm converged.	0,826	1,432
		Black	18	1,0	5	27,8	19	1,0	4	21,1	1,44		Algorithm converged.	0,32	6,53	0,067		Algorithm converged.	-0,209	0,344	1,319		Algorithm converged.	0,420	4,150	0,6354		0,758		Algorithm converged.	0,241	2,384
		Asian	400	22,1	27	6,8	395	21,7	29	7,3	0,91		Algorithm converged.	0,53	1,57	-0,006		Algorithm converged.	-0,041	0,030	0,919		Algorithm converged.	0,555	1,524	0,7445		1,088		Algorithm converged.	0,656	1,803
		Other	44	2,4	4	9,1	33	1,8	5	15,2	0,56		Algorithm converged.	0,14	2,27	-0,061		Algorithm converged.	-0,210	0,088	0,600		Algorithm converged.	0,175	2,063	0,4175		1,667		Algorithm converged.	0,485	5,730
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC02_W15_SG.xls
26OCT2020 16:03

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Pain Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1541	85,1	420	27,3	1597	87,6	461	28,9	0,92		Algorithm converged.	0,79	1,08	-0,016		Algorithm converged.	-0,048	0,015	0,944		Algorithm converged.	0,844	1,056	0,3155		1,059		Algorithm converged.	0,947	1,185
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	15	34,9	35	1,9	9	25,7	1,55		Algorithm converged.	0,58	4,14	0,092		Algorithm converged.	-0,111	0,295	1,357		Algorithm converged.	0,677	2,720	0,3902	0,6168	0,737		Algorithm converged.	0,368	1,478
		0 positive nodes, tumor > 1 cm	225	12,4	61	27,1	248	13,6	80	32,3	0,78		Algorithm converged.	0,53	1,16	-0,051		Algorithm converged.	-0,134	0,031	0,840		Algorithm converged.	0,635	1,112	0,2238		1,190		Algorithm converged.	0,899	1,574
		1-3 positive nodes	770	42,5	210	27,3	796	43,7	228	28,6	0,93		Algorithm converged.	0,75	1,17	-0,014		Algorithm converged.	-0,058	0,031	0,952		Algorithm converged.	0,812	1,116	0,5460		1,050		Algorithm converged.	0,896	1,231
		>= 4 positive nodes	503	27,8	134	26,6	518	28,4	144	27,8	0,94		Algorithm converged.	0,72	1,24	-0,012		Algorithm converged.	-0,066	0,043	0,958		Algorithm converged.	0,784	1,171	0,6775		1,044		Algorithm converged.	0,854	1,275
	Adjuvant chemotherapy regimen	Anthracycline	1233	68,1	335	27,2	1280	70,2	363	28,4	0,94		Algorithm converged.	0,79	1,12	-0,012		Algorithm converged.	-0,047	0,023	0,958		Algorithm converged.	0,844	1,087	0,5057	0,6145	1,044		Algorithm converged.	0,920	1,184
		Non-anthracycline	308	17,0	85	27,6	317	17,4	98	30,9	0,85		Algorithm converged.	0,60	1,20	-0,033		Algorithm converged.	-0,104	0,038	0,893		Algorithm converged.	0,699	1,140	0,3629		1,120		Algorithm converged.	0,877	1,431
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	750	41,4	209	27,9	754	41,4	229	30,4	0,89		Algorithm converged.	0,71	1,11	-0,025		Algorithm converged.	-0,071	0,021	0,918		Algorithm converged.	0,783	1,074	0,2854	0,6316	1,090		Algorithm converged.	0,931	1,276
		Positive (ER and/or PgR positive)	791	43,7	211	26,7	843	46,2	232	27,5	0,96		Algorithm converged.	0,77	1,19	-0,008		Algorithm converged.	-0,052	0,035	0,969		Algorithm converged.	0,827	1,137	0,7008		1,032		Algorithm converged.	0,880	1,210

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	214	11,8	57	26,6	224	12,3	65	29,0	0,89		Algorithm converged.	0,58	1,35	-0,024		Algorithm converged.	-0,108	0,060	0,918		Algorithm converged.	0,678	1,242	0,5786	0,1664	1,089		Algorithm converged.	0,805	1,474
		Western Europe	666	36,8	200	30,0	680	37,3	208	30,6	0,97		Algorithm converged.	0,77	1,23	-0,006		Algorithm converged.	-0,055	0,044	0,982		Algorithm converged.	0,835	1,154	0,8237		1,019		Algorithm converged.	0,866	1,198
		Asia Pacific	461	25,5	119	25,8	488	26,8	119	24,4	1,08		Algorithm converged.	0,80	1,45	0,014		Algorithm converged.	-0,041	0,069	1,059		Algorithm converged.	0,850	1,319	0,6119		0,945		Algorithm converged.	0,758	1,177
		Latin America	38	2,1	9	23,7	42	2,3	14	33,3	0,62		Algorithm converged.	0,23	1,66	-0,096		Algorithm converged.	-0,293	0,100	0,711		Algorithm converged.	0,348	1,450	0,3476		1,407		Algorithm converged.	0,690	2,872
		Other	162	8,9	35	21,6	163	8,9	55	33,7	0,54		Algorithm converged.	0,33	0,89	-0,121		Algorithm converged.	-0,218	-0,025	0,640		Algorithm converged.	0,445	0,921	0,0163		1,562		Algorithm converged.	1,086	2,247
	Protocol version	Protocol A	1051	58,0	278	26,5	1093	60,0	319	29,2	0,87		Algorithm converged.	0,72	1,05	-0,027		Algorithm converged.	-0,065	0,011	0,906		Algorithm converged.	0,790	1,039	0,1584	0,3002	1,103		Algorithm converged.	0,962	1,265
		Protocol amendment B	490	27,1	142	29,0	504	27,6	142	28,2	1,04		Algorithm converged.	0,79	1,37	0,008		Algorithm converged.	-0,048	0,064	1,029		Algorithm converged.	0,845	1,252	0,7788		0,972		Algorithm converged.	0,799	1,183
	Nodal status	0 positive nodes	268	14,8	76	28,4	283	15,5	89	31,4	0,86		Algorithm converged.	0,60	1,24	-0,031		Algorithm converged.	-0,107	0,046	0,902		Algorithm converged.	0,698	1,165	0,4293	0,6956	1,109		Algorithm converged.	0,858	1,433
		>= 1 positive nodes	1273	70,3	344	27,0	1314	72,1	372	28,3	0,94		Algorithm converged.	0,79	1,11	-0,013		Algorithm converged.	-0,047	0,022	0,955		Algorithm converged.	0,843	1,081	0,4644		1,048		Algorithm converged.	0,925	1,187
	Menopausal status at randomization	Premenopausal	753	41,6	191	25,4	798	43,8	218	27,3	0,90		Algorithm converged.	0,72	1,13	-0,020		Algorithm converged.	-0,063	0,024	0,929		Algorithm converged.	0,786	1,097	0,3834	0,8121	1,077		Algorithm converged.	0,912	1,272
		Postmenopausal	784	43,3	227	29,0	791	43,4	240	30,3	0,94		Algorithm converged.	0,75	1,16	-0,014		Algorithm converged.	-0,059	0,031	0,954		Algorithm converged.	0,820	1,111	0,5468		1,048		Algorithm converged.	0,900	1,220
		Unknown/Missing	4	0,2	2	50,0	8	0,4	3	37,5	1,67		Algorithm converged.	0,15	18,87	0,125		Algorithm converged.	-0,469	0,719	1,333		Algorithm converged.	0,354	5,026	0,6709		0,750		Algorithm converged.	0,199	2,827
	Age II	< 65	1360	75,1	360	26,5	1422	78,0	409	28,8	0,89		Algorithm converged.	0,75	1,05	-0,023		Algorithm converged.	-0,056	0,010	0,920		Algorithm converged.	0,816	1,038	0,1771	0,2529	1,087		Algorithm converged.	0,963	1,226
		>= 65	181	10,0	60	33,1	175	9,6	52	29,7	1,17		Algorithm converged.	0,75	1,84	0,034		Algorithm converged.	-0,062	0,131	1,116		Algorithm converged.	0,820	1,518	0,4860		0,896		Algorithm converged.	0,659	1,219

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	14	51,9	22	1,2	7	31,8	2,31		Algorithm converged.	0,71	7,45	0,200		Algorithm converged.	-0,071	0,471	1,630		Algorithm converged.	0,800	3,320	0,1786	0,2479	0,614		Algorithm converged.	0,301	1,250
		Grade 2	473	26,1	126	26,6	486	26,7	134	27,6	0,95		Algorithm converged.	0,72	1,27	-0,009		Algorithm converged.	-0,066	0,047	0,966		Algorithm converged.	0,785	1,189	0,7451		1,035		Algorithm converged.	0,841	1,274
		Grade 3	982	54,2	263	26,8	1030	56,5	302	29,3	0,88		Algorithm converged.	0,73	1,07	-0,025		Algorithm converged.	-0,065	0,014	0,913		Algorithm converged.	0,794	1,051	0,2059		1,095		Algorithm converged.	0,951	1,260
		Unevaluable/Unknown/Missing	59	3,3	17	28,8	59	3,2	18	30,5	0,92		Algorithm converged.	0,42	2,03	-0,017		Algorithm converged.	-0,182	0,148	0,944		Algorithm converged.	0,542	1,647	0,8403		1,059		Algorithm converged.	0,607	1,846
	Type of surgery for primary tumor	Breast conserving surgery	609	33,6	184	30,2	602	33,0	190	31,6	0,94		Algorithm converged.	0,74	1,20	-0,013		Algorithm converged.	-0,066	0,039	0,957		Algorithm converged.	0,809	1,133	0,6117	0,8177	1,045		Algorithm converged.	0,883	1,236
		Mastectomy	932	51,5	236	25,3	994	54,5	270	27,2	0,91		Algorithm converged.	0,74	1,11	-0,018		Algorithm converged.	-0,058	0,021	0,932		Algorithm converged.	0,802	1,083	0,3593		1,073		Algorithm converged.	0,923	1,246
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	569	31,4	156	27,4	581	31,9	176	30,3	0,87		Algorithm converged.	0,67	1,12	-0,029		Algorithm converged.	-0,081	0,024	0,905		Algorithm converged.	0,755	1,086	0,2824	0,7838	1,105		Algorithm converged.	0,921	1,325
		>= 2 - < 5 cm	847	46,8	233	27,5	864	47,4	243	28,1	0,97		Algorithm converged.	0,78	1,20	-0,006		Algorithm converged.	-0,049	0,036	0,978		Algorithm converged.	0,840	1,139	0,7762		1,022		Algorithm converged.	0,878	1,191
		>= 5 cm	123	6,8	30	24,4	150	8,2	41	27,3	0,86		Algorithm converged.	0,50	1,48	-0,029		Algorithm converged.	-0,134	0,075	0,892		Algorithm converged.	0,595	1,339	0,5824		1,121		Algorithm converged.	0,747	1,682
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1191	65,8	340	28,5	1207	66,2	347	28,7	0,99		Algorithm converged.	0,83	1,18	-0,002		Algorithm converged.	-0,038	0,034	0,993		Algorithm converged.	0,875	1,127	0,9131	0,0891	1,007		Algorithm converged.	0,888	1,143
		No	350	19,3	80	22,9	390	21,4	114	29,2	0,72		Algorithm converged.	0,51	1,00	-0,064		Algorithm converged.	-0,127	-0,001	0,782		Algorithm converged.	0,611	1,001	0,0507		1,279		Algorithm converged.	0,999	1,637
	Race	White	1020	56,3	281	27,5	1062	58,3	315	29,7	0,90		Algorithm converged.	0,75	1,09	-0,021		Algorithm converged.	-0,060	0,018	0,929		Algorithm converged.	0,811	1,064	0,2869	0,6033	1,077		Algorithm converged.	0,940	1,233

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	7	33,3	27	1,5	13	48,1	0,54		Algorithm converged.	0,17	1,75	-0,148		Algorithm converged.	-0,424	0,128	0,692		Algorithm converged.	0,337	1,423	0,3171		1,444		Algorithm converged.	0,703	2,969
		Asian	449	24,8	120	26,7	460	25,2	118	25,7	1,06		Algorithm converged.	0,79	1,42	0,011		Algorithm converged.	-0,046	0,068	1,042		Algorithm converged.	0,838	1,296	0,7127		0,960		Algorithm converged.	0,772	1,194
		Other	47	2,6	12	25,5	47	2,6	15	31,9	0,73		Algorithm converged.	0,30	1,80	-0,064		Algorithm converged.	-0,246	0,119	0,800		Algorithm converged.	0,421	1,521	0,4960		1,250		Algorithm converged.	0,657	2,376
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1362	75,2	316	23,2	1328	72,8	318	23,9	0,96		Algorithm converged.	0,80	1,15	-0,007		Algorithm converged.	-0,040	0,025	0,969		Algorithm converged.	0,846	1,110	0,6492		1,032		Algorithm converged.	0,901	1,183
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	9	20,5	35	1,9	5	14,3	1,54		Algorithm converged.	0,47	5,11	0,062		Algorithm converged.	-0,105	0,228	1,432		Algorithm converged.	0,527	3,888	0,4813	0,8198	0,698		Algorithm converged.	0,257	1,897
		0 positive nodes, tumor > 1 cm	213	11,8	49	23,0	222	12,2	53	23,9	0,95		Algorithm converged.	0,61	1,49	-0,009		Algorithm converged.	-0,088	0,071	0,964		Algorithm converged.	0,686	1,354	0,8307		1,038		Algorithm converged.	0,739	1,458
		1-3 positive nodes	693	38,3	163	23,5	657	36,0	166	25,3	0,91		Algorithm converged.	0,71	1,17	-0,017		Algorithm converged.	-0,063	0,028	0,931		Algorithm converged.	0,771	1,123	0,4553		1,074		Algorithm converged.	0,890	1,296
		>= 4 positive nodes	412	22,7	95	23,1	414	22,7	94	22,7	1,02		Algorithm converged.	0,74	1,41	0,004		Algorithm converged.	-0,054	0,061	1,016		Algorithm converged.	0,791	1,305	0,9039		0,985		Algorithm converged.	0,767	1,265
	Adjuvant chemotherapy regimen	Anthracycline	1087	60,0	259	23,8	1067	58,5	248	23,2	1,03		Algorithm converged.	0,85	1,26	0,006		Algorithm converged.	-0,030	0,042	1,025		Algorithm converged.	0,880	1,194	0,7493	0,1039	0,975		Algorithm converged.	0,838	1,136
		Non-anthracycline	275	15,2	57	20,7	261	14,3	70	26,8	0,71		Algorithm converged.	0,48	1,06	-0,061		Algorithm converged.	-0,133	0,011	0,773		Algorithm converged.	0,569	1,049	0,0987		1,294		Algorithm converged.	0,953	1,757
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	664	36,7	147	22,1	644	35,3	154	23,9	0,90		Algorithm converged.	0,70	1,17	-0,018		Algorithm converged.	-0,063	0,028	0,926		Algorithm converged.	0,759	1,129	0,4460	0,5323	1,080		Algorithm converged.	0,886	1,317

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	698	38,5	169	24,2	684	37,5	164	24,0	1,01		Algorithm converged.	0,79	1,30	0,002		Algorithm converged.	-0,043	0,047	1,010		Algorithm converged.	0,837	1,218	0,9185		0,990		Algorithm converged.	0,821	1,194
	Geographical region II	USA/Canada	178	9,8	46	25,8	155	8,5	37	23,9	1,11		Algorithm converged.	0,67	1,83	0,020		Algorithm converged.	-0,073	0,113	1,083		Algorithm converged.	0,744	1,576	0,6787	0,1990	0,924		Algorithm converged.	0,635	1,345
		Western Europe	588	32,5	153	26,0	578	31,7	168	29,1	0,86		Algorithm converged.	0,66	1,11	-0,030		Algorithm converged.	-0,082	0,021	0,895		Algorithm converged.	0,743	1,079	0,2449		1,117		Algorithm converged.	0,927	1,346
		Asia Pacific	415	22,9	79	19,0	428	23,5	77	18,0	1,07		Algorithm converged.	0,76	1,52	0,010		Algorithm converged.	-0,042	0,063	1,058		Algorithm converged.	0,797	1,405	0,6960		0,945		Algorithm converged.	0,712	1,255
		Latin America	34	1,9	11	32,4	36	2,0	5	13,9	2,97		Algorithm converged.	0,90	9,72	0,185		Algorithm converged.	-0,009	0,378	2,329		Algorithm converged.	0,903	6,008	0,0803		0,429		Algorithm converged.	0,166	1,107
		Other	147	8,1	27	18,4	131	7,2	31	23,7	0,73		Algorithm converged.	0,41	1,30	-0,053		Algorithm converged.	-0,149	0,043	0,776		Algorithm converged.	0,490	1,228	0,2793		1,288		Algorithm converged.	0,814	2,039
	Protocol version	Protocol A	957	52,8	212	22,2	918	50,4	227	24,7	0,87		Algorithm converged.	0,70	1,07	-0,026		Algorithm converged.	-0,064	0,013	0,896		Algorithm converged.	0,760	1,055	0,1883	0,0890	1,116		Algorithm converged.	0,948	1,315
		Protocol amendment B	405	22,4	104	25,7	410	22,5	91	22,2	1,21		Algorithm converged.	0,88	1,67	0,035		Algorithm converged.	-0,024	0,093	1,157		Algorithm converged.	0,905	1,479	0,2445		0,864		Algorithm converged.	0,676	1,105
	Nodal status	0 positive nodes	257	14,2	58	22,6	257	14,1	58	22,6	1,00		Algorithm converged.	0,66	1,51	0,000		Algorithm converged.	-0,072	0,072	1,000		Algorithm converged.	0,726	1,377	1,0000	0,8291	1,000		Algorithm converged.	0,726	1,377
		>= 1 positive nodes	1105	61,0	258	23,3	1071	58,7	260	24,3	0,95		Algorithm converged.	0,78	1,16	-0,009		Algorithm converged.	-0,045	0,027	0,962		Algorithm converged.	0,828	1,118	0,6114		1,040		Algorithm converged.	0,895	1,208
	Menopausal status at randomization	Premenopausal	662	36,6	138	20,8	660	36,2	149	22,6	0,90		Algorithm converged.	0,70	1,17	-0,017		Algorithm converged.	-0,062	0,027	0,923		Algorithm converged.	0,752	1,133	0,4458	0,5587	1,083		Algorithm converged.	0,882	1,329
		Postmenopausal	696	38,4	177	25,4	662	36,3	168	25,4	1,00		Algorithm converged.	0,79	1,28	0,001		Algorithm converged.	-0,046	0,047	1,002		Algorithm converged.	0,835	1,203	0,9820		0,998		Algorithm converged.	0,832	1,197
		Unknown/Missing	4	0,2	1	25,0	6	0,3	1	16,7	1,67		Algorithm converged.	0,07	37,73	0,083		Algorithm converged.	-0,435	0,602	1,500		Algorithm converged.	0,127	17,667	0,7473		0,667		Algorithm converged.	0,057	7,852

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Age II	< 65	1209	66,8	269	22,2	1186	65,1	286	24,1	0,90		Algorithm converged.	0,74	1,09	-0,019		Algorithm converged.	-0,052	0,015	0,923		Algorithm converged.	0,797	1,068	0,2797	0,0611	1,084		Algorithm converged.	0,937	1,254
		>= 65	153	8,4	47	30,7	142	7,8	32	22,5	1,52		Algorithm converged.	0,90	2,57	0,082		Algorithm converged.	-0,018	0,182	1,363		Algorithm converged.	0,926	2,007	0,1165		0,734		Algorithm converged.	0,498	1,080
	Histological grade	Grade 1	26	1,4	8	30,8	20	1,1	8	40,0	0,67		Algorithm converged.	0,20	2,26	-0,092		Algorithm converged.	-0,371	0,186	0,769		Algorithm converged.	0,350	1,691	0,5139	0,7343	1,300		Algorithm converged.	0,591	2,858
		Grade 2	428	23,6	95	22,2	407	22,3	96	23,6	0,92		Algorithm converged.	0,67	1,28	-0,014		Algorithm converged.	-0,071	0,043	0,941		Algorithm converged.	0,734	1,207	0,6324		1,063		Algorithm converged.	0,828	1,363
		Grade 3	859	47,4	208	24,2	850	46,6	203	23,9	1,02		Algorithm converged.	0,82	1,27	0,003		Algorithm converged.	-0,037	0,044	1,014		Algorithm converged.	0,857	1,200	0,8725		0,986		Algorithm converged.	0,833	1,167
		Unevaluable/Unknown/Missing	49	2,7	5	10,2	51	2,8	11	21,6	0,41		Algorithm converged.	0,13	1,29	-0,114		Algorithm converged.	-0,255	0,028	0,473		Algorithm converged.	0,177	1,263	0,1351		2,114		Algorithm converged.	0,792	5,642
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	127	23,2	520	28,5	140	26,9	0,82		Algorithm converged.	0,62	1,08	-0,037		Algorithm converged.	-0,089	0,015	0,862		Algorithm converged.	0,700	1,062	0,1630	0,1552	1,160		Algorithm converged.	0,942	1,428
		Mastectomy	815	45,0	189	23,2	808	44,3	178	22,0	1,07		Algorithm converged.	0,85	1,35	0,012		Algorithm converged.	-0,029	0,052	1,053		Algorithm converged.	0,879	1,260	0,5764		0,950		Algorithm converged.	0,793	1,137
	Tumor size	0 - < 2 cm	516	28,5	112	21,7	491	26,9	124	25,3	0,82		Algorithm converged.	0,61	1,10	-0,035		Algorithm converged.	-0,088	0,017	0,859		Algorithm converged.	0,687	1,075	0,1844	0,3365	1,164		Algorithm converged.	0,930	1,455
		>= 2 - < 5 cm	744	41,1	181	24,3	721	39,6	165	22,9	1,08		Algorithm converged.	0,85	1,38	0,014		Algorithm converged.	-0,029	0,058	1,063		Algorithm converged.	0,884	1,278	0,5158		0,941		Algorithm converged.	0,782	1,131
		>= 5 cm	100	5,5	22	22,0	114	6,3	28	24,6	0,87		Algorithm converged.	0,46	1,64	-0,026		Algorithm converged.	-0,139	0,088	0,896		Algorithm converged.	0,549	1,461	0,6593		1,116		Algorithm converged.	0,684	1,822
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1041	57,5	250	24,0	1013	55,6	250	24,7	0,96		Algorithm converged.	0,79	1,18	-0,007		Algorithm converged.	-0,044	0,030	0,973		Algorithm converged.	0,835	1,133	0,7260	0,9008	1,028		Algorithm converged.	0,882	1,197

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		No	321	17,7	66	20,6	315	17,3	68	21,6	0,94		Algorithm converged.	0,64	1,38	-0,010		Algorithm converged.	-0,074	0,053	0,952		Algorithm converged.	0,705	1,287	0,7510		1,050		Algorithm converged.	0,777	1,419
	Race	White	896	49,5	219	24,4	880	48,3	231	26,3	0,91		Algorithm converged.	0,73	1,13	-0,018		Algorithm converged.	-0,059	0,022	0,931		Algorithm converged.	0,794	1,092	0,3812	0,3655	1,074		Algorithm converged.	0,915	1,260
		Black	18	1,0	5	27,8	19	1,0	7	36,8	0,66		Algorithm converged.	0,16	2,65	-0,091		Algorithm converged.	-0,390	0,209	0,754		Algorithm converged.	0,292	1,948	0,5599		1,326		Algorithm converged.	0,513	3,428
		Asian	399	22,0	78	19,5	395	21,7	75	19,0	1,04		Algorithm converged.	0,73	1,48	0,006		Algorithm converged.	-0,049	0,060	1,030		Algorithm converged.	0,774	1,369	0,8410		0,971		Algorithm converged.	0,731	1,291
		Other	44	2,4	13	29,5	33	1,8	5	15,2	2,35		Algorithm converged.	0,74	7,42	0,144		Algorithm converged.	-0,038	0,326	1,950		Algorithm converged.	0,771	4,929	0,1581		0,513		Algorithm converged.	0,203	1,296
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC03_W15_SG.xls
26OCT2020 16:07

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Dyspnea Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1539	85,0	392	25,5	1592	87,3	375	23,6	1,11		Algorithm converged.	0,94	1,31	0,019		Algorithm converged.	-0,011	0,049	1,081		Algorithm converged.	0,956	1,223	0,2128		0,925		Algorithm converged.	0,818	1,046
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	8	18,6	35	1,9	11	31,4	0,50		Algorithm converged.	0,17	1,42	-0,128		Algorithm converged.	-0,321	0,065	0,592		Algorithm converged.	0,268	1,309	0,1955	0,2111	1,689		Algorithm converged.	0,764	3,737
		0 positive nodes, tumor > 1 cm	225	12,4	66	29,3	245	13,4	58	23,7	1,34		Algorithm converged.	0,89	2,02	0,057		Algorithm converged.	-0,023	0,136	1,239		Algorithm converged.	0,915	1,677	0,1653		0,807		Algorithm converged.	0,596	1,092
		1-3 positive nodes	769	42,5	183	23,8	795	43,6	189	23,8	1,00		Algorithm converged.	0,79	1,26	0,000		Algorithm converged.	-0,042	0,042	1,001		Algorithm converged.	0,838	1,195	0,9913		0,999		Algorithm converged.	0,837	1,193
		>= 4 positive nodes	502	27,7	135	26,9	517	28,4	117	22,6	1,26		Algorithm converged.	0,95	1,67	0,043		Algorithm converged.	-0,010	0,096	1,188		Algorithm converged.	0,958	1,473	0,1157		0,842		Algorithm converged.	0,679	1,043
	Adjuvant chemotherapy regimen	Anthracycline	1233	68,1	308	25,0	1277	70,0	286	22,4	1,15		Algorithm converged.	0,96	1,39	0,026		Algorithm converged.	-0,007	0,059	1,115		Algorithm converged.	0,969	1,284	0,1282	0,3503	0,897		Algorithm converged.	0,779	1,032
		Non-anthracycline	306	16,9	84	27,5	315	17,3	89	28,3	0,96		Algorithm converged.	0,68	1,36	-0,008		Algorithm converged.	-0,079	0,062	0,972		Algorithm converged.	0,754	1,252	0,8234		1,029		Algorithm converged.	0,799	1,326
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	750	41,4	185	24,7	750	41,1	184	24,5	1,01		Algorithm converged.	0,80	1,27	0,001		Algorithm converged.	-0,042	0,045	1,005		Algorithm converged.	0,842	1,200	0,9522	0,2649	0,995		Algorithm converged.	0,833	1,187
		Positive (ER and/or PgR positive)	789	43,6	207	26,2	842	46,2	191	22,7	1,21		Algorithm converged.	0,97	1,52	0,036		Algorithm converged.	-0,006	0,077	1,157		Algorithm converged.	0,975	1,372	0,0955		0,865		Algorithm converged.	0,729	1,026

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	214	11,8	47	22,0	223	12,2	45	20,2	1,11		Algorithm converged.	0,70	1,76	0,018		Algorithm converged.	-0,059	0,094	1,088		Algorithm converged.	0,757	1,565	0,6477	0,7551	0,919		Algorithm converged.	0,639	1,321
		Western Europe	664	36,7	197	29,7	677	37,1	176	26,0	1,20		Algorithm converged.	0,95	1,53	0,037		Algorithm converged.	-0,011	0,085	1,141		Algorithm converged.	0,960	1,357	0,1341		0,876		Algorithm converged.	0,737	1,042
		Asia Pacific	461	25,5	108	23,4	488	26,8	111	22,7	1,04		Algorithm converged.	0,77	1,41	0,007		Algorithm converged.	-0,047	0,060	1,030		Algorithm converged.	0,816	1,299	0,8033		0,971		Algorithm converged.	0,770	1,225
		Latin America	38	2,1	5	13,2	42	2,3	9	21,4	0,56		Algorithm converged.	0,17	1,84	-0,083		Algorithm converged.	-0,247	0,081	0,614		Algorithm converged.	0,226	1,671	0,3398		1,629		Algorithm converged.	0,598	4,433
		Other	162	8,9	35	21,6	162	8,9	34	21,0	1,04		Algorithm converged.	0,61	1,77	0,006		Algorithm converged.	-0,083	0,095	1,029		Algorithm converged.	0,677	1,565	0,8921		0,971		Algorithm converged.	0,639	1,477
	Protocol version	Protocol A	1052	58,1	275	26,1	1088	59,7	243	22,3	1,23		Algorithm converged.	1,01	1,50	0,038		Algorithm converged.	0,002	0,074	1,170		Algorithm converged.	1,007	1,360	0,0402	0,0687	0,854		Algorithm converged.	0,735	0,993
		Protocol amendment B	487	26,9	117	24,0	504	27,6	132	26,2	0,89		Algorithm converged.	0,67	1,19	-0,022		Algorithm converged.	-0,076	0,032	0,917		Algorithm converged.	0,740	1,138	0,4324		1,090		Algorithm converged.	0,879	1,352
	Nodal status	0 positive nodes	268	14,8	74	27,6	280	15,4	69	24,6	1,17		Algorithm converged.	0,80	1,71	0,030		Algorithm converged.	-0,044	0,103	1,120		Algorithm converged.	0,845	1,486	0,4292	0,7853	0,892		Algorithm converged.	0,673	1,183
		>= 1 positive nodes	1271	70,2	318	25,0	1312	72,0	306	23,3	1,10		Algorithm converged.	0,92	1,31	0,017		Algorithm converged.	-0,016	0,050	1,073		Algorithm converged.	0,936	1,230	0,3140		0,932		Algorithm converged.	0,813	1,069
	Menopausal status at randomization	Premenopausal	754	41,6	179	23,7	796	43,7	176	22,1	1,10		Algorithm converged.	0,87	1,39	0,016		Algorithm converged.	-0,026	0,058	1,074		Algorithm converged.	0,894	1,289	0,4455	0,9911	0,931		Algorithm converged.	0,776	1,118
		Postmenopausal	781	43,1	211	27,0	788	43,2	198	25,1	1,10		Algorithm converged.	0,88	1,38	0,019		Algorithm converged.	-0,025	0,062	1,075		Algorithm converged.	0,910	1,270	0,3941		0,930		Algorithm converged.	0,787	1,099
		Unknown/Missing	4	0,2	2	50,0	8	0,4	1	12,5	7,00		Algorithm converged.	0,40	123,35	0,375		Algorithm converged.	-0,166	0,916	4,000		Algorithm converged.	0,500	31,981	0,1912		0,250		Algorithm converged.	0,031	1,999
	Age II	< 65	1359	75,0	329	24,2	1419	77,8	327	23,0	1,07		Algorithm converged.	0,90	1,27	0,012		Algorithm converged.	-0,020	0,043	1,051		Algorithm converged.	0,919	1,201	0,4700	0,2887	0,952		Algorithm converged.	0,833	1,088
		>= 65	180	9,9	63	35,0	173	9,5	48	27,7	1,40		Algorithm converged.	0,89	2,20	0,073		Algorithm converged.	-0,024	0,169	1,261		Algorithm converged.	0,923	1,724	0,1448		0,793		Algorithm converged.	0,580	1,083

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	6	22,2	22	1,2	7	31,8	0,61		Algorithm converged.	0,17	2,19	-0,096		Algorithm converged.	-0,346	0,154	0,698		Algorithm converged.	0,274	1,777	0,4513	0,6321	1,432		Algorithm converged.	0,563	3,643
		Grade 2	472	26,1	126	26,7	484	26,5	116	24,0	1,16		Algorithm converged.	0,86	1,55	0,027		Algorithm converged.	-0,028	0,082	1,114		Algorithm converged.	0,896	1,385	0,3325		0,898		Algorithm converged.	0,722	1,117
		Grade 3	981	54,2	248	25,3	1027	56,3	241	23,5	1,10		Algorithm converged.	0,90	1,35	0,018		Algorithm converged.	-0,019	0,056	1,077		Algorithm converged.	0,923	1,257	0,3439		0,928		Algorithm converged.	0,796	1,083
		Unevaluable/Unknown/Missing	59	3,3	12	20,3	59	3,2	11	18,6	1,11		Algorithm converged.	0,45	2,77	0,017		Algorithm converged.	-0,126	0,160	1,091		Algorithm converged.	0,523	2,273	0,8163		0,917		Algorithm converged.	0,440	1,910
	Type of surgery for primary tumor	Breast conserving surgery	608	33,6	166	27,3	600	32,9	147	24,5	1,16		Algorithm converged.	0,89	1,50	0,028		Algorithm converged.	-0,021	0,077	1,114		Algorithm converged.	0,920	1,349	0,2669	0,6934	0,897		Algorithm converged.	0,741	1,086
		Mastectomy	931	51,4	226	24,3	991	54,4	227	22,9	1,08		Algorithm converged.	0,87	1,33	0,014		Algorithm converged.	-0,024	0,052	1,060		Algorithm converged.	0,902	1,245	0,4798		0,944		Algorithm converged.	0,803	1,108
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	567	31,3	145	25,6	581	31,9	143	24,6	1,05		Algorithm converged.	0,81	1,37	0,010		Algorithm converged.	-0,041	0,060	1,039		Algorithm converged.	0,851	1,269	0,7074	0,8212	0,962		Algorithm converged.	0,788	1,175
		>= 2 - < 5 cm	847	46,8	209	24,7	860	47,2	193	22,4	1,13		Algorithm converged.	0,91	1,42	0,022		Algorithm converged.	-0,018	0,063	1,100		Algorithm converged.	0,927	1,305	0,2772		0,909		Algorithm converged.	0,766	1,079
		>= 5 cm	123	6,8	38	30,9	149	8,2	39	26,2	1,26		Algorithm converged.	0,74	2,14	0,047		Algorithm converged.	-0,061	0,155	1,180		Algorithm converged.	0,809	1,722	0,3895		0,847		Algorithm converged.	0,581	1,236
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1190	65,7	322	27,1	1204	66,0	289	24,0	1,17		Algorithm converged.	0,98	1,41	0,031		Algorithm converged.	-0,004	0,065	1,127		Algorithm converged.	0,983	1,293	0,0868	0,1665	0,887		Algorithm converged.	0,773	1,017
		No	349	19,3	70	20,1	388	21,3	86	22,2	0,88		Algorithm converged.	0,62	1,26	-0,021		Algorithm converged.	-0,080	0,038	0,905		Algorithm converged.	0,684	1,198	0,4850		1,105		Algorithm converged.	0,835	1,463
	Race	White	1017	56,2	273	26,8	1057	58,0	255	24,1	1,15		Algorithm converged.	0,95	1,41	0,027		Algorithm converged.	-0,010	0,065	1,113		Algorithm converged.	0,960	1,289	0,1556	0,8320	0,899		Algorithm converged.	0,776	1,041

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	8	38,1	27	1,5	11	40,7	0,90		Algorithm converged.	0,28	2,88	-0,026		Algorithm converged.	-0,305	0,252	0,935		Algorithm converged.	0,460	1,902	0,8530		1,069		Algorithm converged.	0,526	2,175
		Asian	450	24,8	103	22,9	460	25,2	100	21,7	1,07		Algorithm converged.	0,78	1,46	0,011		Algorithm converged.	-0,043	0,066	1,053		Algorithm converged.	0,826	1,342	0,6771		0,950		Algorithm converged.	0,745	1,210
		Other	47	2,6	7	14,9	47	2,6	9	19,1	0,74		Algorithm converged.	0,25	2,18	-0,043		Algorithm converged.	-0,194	0,109	0,778		Algorithm converged.	0,316	1,915	0,5847		1,286		Algorithm converged.	0,522	3,166
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1361	75,2	278	20,4	1321	72,5	303	22,9	0,86		Algorithm converged.	0,72	1,04	-0,025		Algorithm converged.	-0,056	0,006	0,891		Algorithm converged.	0,771	1,029	0,1148		1,123		Algorithm converged.	0,972	1,297
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	3	6,8	35	1,9	7	20,0	0,29		Algorithm converged.	0,07	1,23	-0,132		Algorithm converged.	-0,284	0,020	0,341		Algorithm converged.	0,095	1,223	0,0988	0,2593	2,933		Algorithm converged.	0,818	10,525
		0 positive nodes, tumor > 1 cm	213	11,8	45	21,1	222	12,2	60	27,0	0,72		Algorithm converged.	0,46	1,13	-0,059		Algorithm converged.	-0,139	0,021	0,782		Algorithm converged.	0,558	1,096	0,1529		1,279		Algorithm converged.	0,913	1,793
		1-3 positive nodes	692	38,2	145	21,0	651	35,7	138	21,2	0,99		Algorithm converged.	0,76	1,28	-0,002		Algorithm converged.	-0,046	0,041	0,988		Algorithm converged.	0,804	1,216	0,9126		1,012		Algorithm converged.	0,822	1,244
		>= 4 positive nodes	412	22,7	85	20,6	413	22,7	98	23,7	0,84		Algorithm converged.	0,60	1,16	-0,031		Algorithm converged.	-0,088	0,026	0,869		Algorithm converged.	0,673	1,124	0,2850		1,150		Algorithm converged.	0,890	1,486
	Adjuvant chemotherapy regimen	Anthracycline	1087	60,0	226	20,8	1061	58,2	234	22,1	0,93		Algorithm converged.	0,75	1,14	-0,013		Algorithm converged.	-0,047	0,022	0,943		Algorithm converged.	0,802	1,109	0,4755	0,1267	1,061		Algorithm converged.	0,902	1,247

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	274	15,1	52	19,0	260	14,3	69	26,5	0,65		Algorithm converged.	0,43	0,98	-0,076		Algorithm converged.	-0,147	-0,005	0,715		Algorithm converged.	0,521	0,982	0,0384		1,398		Algorithm converged.	1,018	1,921
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	118	17,7	642	35,2	147	22,9	0,73		Algorithm converged.	0,55	0,95	-0,052		Algorithm converged.	-0,095	-0,008	0,775		Algorithm converged.	0,624	0,962	0,0211	0,0841	1,290		Algorithm converged.	1,039	1,603
		Positive (ER and/or PgR positive)	696	38,4	160	23,0	679	37,2	156	23,0	1,00		Algorithm converged.	0,78	1,29	0,000		Algorithm converged.	-0,044	0,045	1,001		Algorithm converged.	0,825	1,214	0,9952		0,999		Algorithm converged.	0,824	1,213
	Geographical region II	USA/Canada	178	9,8	31	17,4	154	8,4	32	20,8	0,80		Algorithm converged.	0,46	1,39	-0,034		Algorithm converged.	-0,119	0,051	0,838		Algorithm converged.	0,537	1,307	0,4360	-	1,193		Algorithm converged.	0,765	1,861
		Western Europe	587	32,4	147	25,0	573	31,4	152	26,5	0,93		Algorithm converged.	0,71	1,20	-0,015		Algorithm converged.	-0,065	0,036	0,944		Algorithm converged.	0,777	1,148	0,5634		1,059		Algorithm converged.	0,871	1,288
		Asia Pacific	415	22,9	70	16,9	428	23,5	85	19,9	0,82		Algorithm converged.	0,58	1,16	-0,030		Algorithm converged.	-0,082	0,022	0,849		Algorithm converged.	0,638	1,131	0,2632		1,177		Algorithm converged.	0,884	1,567
		Latin America	34	1,9	1	2,9	36	2,0	7	19,4	0,13		Algorithm converged.	0,01	1,08	-0,165		Algorithm converged.	-0,306	-0,024	0,151		Algorithm converged.	0,020	1,166	0,0699		6,611		Algorithm converged.	0,858	50,955
		Other	147	8,1	29	19,7	130	7,1	27	20,8	0,94		Algorithm converged.	0,52	1,69	-0,010		Algorithm converged.	-0,105	0,084	0,950		Algorithm converged.	0,595	1,517	0,8294		1,053		Algorithm converged.	0,659	1,681
	Protocol version	Protocol A	958	52,9	191	19,9	914	50,1	215	23,5	0,81		Algorithm converged.	0,65	1,01	-0,036		Algorithm converged.	-0,073	0,002	0,848		Algorithm converged.	0,713	1,007	0,0603	0,3067	1,180		Algorithm converged.	0,993	1,402
		Protocol amendment B	403	22,3	87	21,6	407	22,3	88	21,6	1,00		Algorithm converged.	0,71	1,39	0,000		Algorithm converged.	-0,057	0,056	0,998		Algorithm converged.	0,768	1,298	0,9907		1,002		Algorithm converged.	0,770	1,302
	Nodal status	0 positive nodes	257	14,2	48	18,7	257	14,1	67	26,1	0,65		Algorithm converged.	0,43	0,99	-0,074		Algorithm converged.	-0,146	-0,002	0,716		Algorithm converged.	0,516	0,994	0,0462	0,1436	1,396		Algorithm converged.	1,006	1,937
		>= 1 positive nodes	1104	61,0	230	20,8	1064	58,4	236	22,2	0,92		Algorithm converged.	0,75	1,13	-0,013		Algorithm converged.	-0,048	0,021	0,939		Algorithm converged.	0,800	1,103	0,4453		1,065		Algorithm converged.	0,906	1,251
	Menopausal status at randomization	Premenopausal	663	36,6	116	17,5	657	36,0	136	20,7	0,81		Algorithm converged.	0,62	1,07	-0,032		Algorithm converged.	-0,074	0,010	0,845		Algorithm converged.	0,676	1,056	0,1394	0,5646	1,183		Algorithm converged.	0,947	1,479

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	694	38,3	161	23,2	659	36,1	166	25,2	0,90		Algorithm converged.	0,70	1,15	-0,020		Algorithm converged.	-0,066	0,026	0,921		Algorithm converged.	0,763	1,112	0,3927		1,086		Algorithm converged.	0,899	1,311
		Unknown/Missing	4	0,2	1	25,0	5	0,3	1	20,0	1,33		Algorithm converged.	0,06	31,12	0,050		Algorithm converged.	-0,500	0,600	1,250		Algorithm converged.	0,109	14,343	0,8578		0,800		Algorithm converged.	0,070	9,180
	Age II	< 65	1208	66,7	234	19,4	1180	64,7	264	22,4	0,83		Algorithm converged.	0,68	1,02	-0,030		Algorithm converged.	-0,063	0,003	0,866		Algorithm converged.	0,740	1,013	0,0714	0,3661	1,155		Algorithm converged.	0,988	1,351
		>= 65	153	8,4	44	28,8	141	7,7	39	27,7	1,06		Algorithm converged.	0,63	1,76	0,011		Algorithm converged.	-0,092	0,114	1,040		Algorithm converged.	0,722	1,498	0,8345		0,962		Algorithm converged.	0,667	1,386
	Histological grade	Grade 1	26	1,4	4	15,4	20	1,1	6	30,0	0,42		Algorithm converged.	0,10	1,78	-0,146		Algorithm converged.	-0,390	0,098	0,513		Algorithm converged.	0,167	1,576	0,2437	0,5833	1,950		Algorithm converged.	0,634	5,993
		Grade 2	427	23,6	91	21,3	404	22,2	95	23,5	0,88		Algorithm converged.	0,64	1,22	-0,022		Algorithm converged.	-0,079	0,035	0,906		Algorithm converged.	0,704	1,168	0,4464		1,103		Algorithm converged.	0,857	1,421
		Grade 3	859	47,4	175	20,4	846	46,4	186	22,0	0,91		Algorithm converged.	0,72	1,15	-0,016		Algorithm converged.	-0,055	0,023	0,927		Algorithm converged.	0,771	1,113	0,4151		1,079		Algorithm converged.	0,898	1,296
		Unevaluable/Unknown/Missing	49	2,7	8	16,3	51	2,8	16	31,4	0,43		Algorithm converged.	0,16	1,12	-0,150		Algorithm converged.	-0,315	0,014	0,520		Algorithm converged.	0,245	1,105	0,0890		1,922		Algorithm converged.	0,905	4,079
	Type of surgery for primary tumor	Breast conserving surgery	546	30,1	124	22,7	516	28,3	118	22,9	0,99		Algorithm converged.	0,74	1,32	-0,002		Algorithm converged.	-0,052	0,049	0,993		Algorithm converged.	0,796	1,239	0,9512	0,2046	1,007		Algorithm converged.	0,807	1,257
		Mastectomy	815	45,0	154	18,9	805	44,2	185	23,0	0,78		Algorithm converged.	0,61	0,99	-0,041		Algorithm converged.	-0,080	-0,001	0,822		Algorithm converged.	0,680	0,995	0,0438		1,216		Algorithm converged.	1,005	1,471
	Tumor size	0 - < 2 cm	514	28,4	104	20,2	490	26,9	114	23,3	0,84		Algorithm converged.	0,62	1,13	-0,030		Algorithm converged.	-0,081	0,021	0,870		Algorithm converged.	0,687	1,100	0,2446	0,7963	1,150		Algorithm converged.	0,909	1,455
		>= 2 - < 5 cm	745	41,1	153	20,5	717	39,3	159	22,2	0,91		Algorithm converged.	0,71	1,16	-0,016		Algorithm converged.	-0,058	0,026	0,926		Algorithm converged.	0,761	1,128	0,4446		1,080		Algorithm converged.	0,887	1,315
		>= 5 cm	100	5,5	21	21,0	112	6,1	30	26,8	0,73		Algorithm converged.	0,38	1,37	-0,058		Algorithm converged.	-0,172	0,057	0,784		Algorithm converged.	0,481	1,277	0,3285		1,276		Algorithm converged.	0,783	2,078
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1040	57,4	226	21,7	1006	55,2	230	22,9	0,94		Algorithm converged.	0,76	1,15	-0,011		Algorithm converged.	-0,047	0,025	0,950		Algorithm converged.	0,808	1,117	0,5385	0,0908	1,052		Algorithm converged.	0,895	1,237
		No	321	17,7	52	16,2	315	17,3	73	23,2	0,64		Algorithm converged.	0,43	0,95	-0,070		Algorithm converged.	-0,131	-0,008	0,699		Algorithm converged.	0,508	0,963	0,0282		1,431		Algorithm converged.	1,039	1,970
	Race	White	894	49,4	203	22,7	873	47,9	215	24,6	0,90		Algorithm converged.	0,72	1,12	-0,019		Algorithm converged.	-0,059	0,020	0,922		Algorithm converged.	0,780	1,090	0,3423	-	1,085		Algorithm converged.	0,917	1,283
		Black	18	1,0	3	16,7	19	1,0	4	21,1	0,75		Algorithm converged.	0,14	3,94	-0,044		Algorithm converged.	-0,295	0,208	0,792		Algorithm converged.	0,205	3,057	0,7347		1,263		Algorithm converged.	0,327	4,878
		Asian	400	22,1	69	17,3	395	21,7	80	20,3	0,82		Algorithm converged.	0,57	1,17	-0,030		Algorithm converged.	-0,084	0,024	0,852		Algorithm converged.	0,637	1,139	0,2788		1,174		Algorithm converged.	0,878	1,570
		Other	44	2,4	2	4,5	33	1,8	4	12,1	0,35		Algorithm converged.	0,06	2,01	-0,076		Algorithm converged.	-0,203	0,051	0,375		Algorithm converged.	0,073	1,926	0,2401		2,667		Algorithm converged.	0,519	13,696
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC04_W15_SG.xls
26OCT2020 16:10

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Insomnia Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	430	28,0	1591	87,3	405	25,5	1,14		Algorithm converged.	0,97	1,33	0,025		Algorithm converged.	-0,006	0,056	1,098		Algorithm converged.	0,978	1,234	0,1138		0,910		Algorithm converged.	0,811	1,023
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	13	30,2	34	1,9	5	14,7	2,51		Algorithm converged.	0,80	7,94	0,155		Algorithm converged.	-0,026	0,337	2,056		Algorithm converged.	0,813	5,201	0,1281	0,5610	0,486		Algorithm converged.	0,192	1,231
		0 positive nodes, tumor > 1 cm	224	12,4	69	30,8	248	13,6	69	27,8	1,15		Algorithm converged.	0,78	1,72	0,030		Algorithm converged.	-0,052	0,112	1,107		Algorithm converged.	0,836	1,466	0,4770		0,903		Algorithm converged.	0,682	1,196
		1-3 positive nodes	770	42,5	212	27,5	795	43,6	204	25,7	1,10		Algorithm converged.	0,88	1,38	0,019		Algorithm converged.	-0,025	0,063	1,073		Algorithm converged.	0,910	1,265	0,4021		0,932		Algorithm converged.	0,790	1,099
		>= 4 positive nodes	501	27,7	136	27,1	514	28,2	127	24,7	1,14		Algorithm converged.	0,86	1,50	0,024		Algorithm converged.	-0,030	0,078	1,099		Algorithm converged.	0,892	1,353	0,3758		0,910		Algorithm converged.	0,739	1,121
	Adjuvant chemotherapy regimen	Anthracycline	1231	68,0	337	27,4	1275	69,9	336	26,4	1,05		Algorithm converged.	0,88	1,26	0,010		Algorithm converged.	-0,024	0,045	1,039		Algorithm converged.	0,913	1,182	0,5634	0,0558	0,963		Algorithm converged.	0,846	1,095
		Non-anthracycline	307	17,0	93	30,3	316	17,3	69	21,8	1,56		Algorithm converged.	1,08	2,23	0,085		Algorithm converged.	0,016	0,153	1,387		Algorithm converged.	1,060	1,815	0,0170		0,721		Algorithm converged.	0,551	0,943
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	748	41,3	206	27,5	751	41,2	193	25,7	1,10		Algorithm converged.	0,87	1,38	0,018		Algorithm converged.	-0,026	0,063	1,072		Algorithm converged.	0,906	1,268	0,4202	0,6907	0,933		Algorithm converged.	0,789	1,104
		Positive (ER and/or PgR positive)	790	43,6	224	28,4	840	46,1	212	25,2	1,17		Algorithm converged.	0,94	1,46	0,031		Algorithm converged.	-0,012	0,074	1,123		Algorithm converged.	0,957	1,319	0,1557		0,890		Algorithm converged.	0,758	1,045

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	214	11,8	67	31,3	223	12,2	51	22,9	1,54		Algorithm converged.	1,00	2,35	0,084		Algorithm converged.	0,001	0,167	1,369		Algorithm converged.	1,002	1,871	0,0487	0,4174	0,730		Algorithm converged.	0,535	0,998
		Western Europe	663	36,6	204	30,8	677	37,1	187	27,6	1,16		Algorithm converged.	0,92	1,47	0,031		Algorithm converged.	-0,017	0,080	1,114		Algorithm converged.	0,943	1,316	0,2055		0,898		Algorithm converged.	0,760	1,061
		Asia Pacific	461	25,5	110	23,9	488	26,8	122	25,0	0,94		Algorithm converged.	0,70	1,26	-0,011		Algorithm converged.	-0,066	0,043	0,954		Algorithm converged.	0,763	1,194	0,6834		1,048		Algorithm converged.	0,837	1,311
		Latin America	38	2,1	5	13,2	42	2,3	7	16,7	0,76		Algorithm converged.	0,22	2,62	-0,035		Algorithm converged.	-0,191	0,121	0,789		Algorithm converged.	0,273	2,280	0,6622		1,267		Algorithm converged.	0,439	3,658
		Other	162	8,9	44	27,2	161	8,8	38	23,6	1,21		Algorithm converged.	0,73	1,99	0,036		Algorithm converged.	-0,059	0,130	1,151		Algorithm converged.	0,791	1,675	0,4633		0,869		Algorithm converged.	0,597	1,265
	Protocol version	Protocol A	1051	58,0	280	26,6	1089	59,7	282	25,9	1,04		Algorithm converged.	0,86	1,26	0,007		Algorithm converged.	-0,030	0,045	1,029		Algorithm converged.	0,893	1,186	0,6950	0,1124	0,972		Algorithm converged.	0,843	1,120
		Protocol amendment B	487	26,9	150	30,8	502	27,5	123	24,5	1,37		Algorithm converged.	1,04	1,81	0,063		Algorithm converged.	0,007	0,119	1,257		Algorithm converged.	1,026	1,540	0,0274		0,795		Algorithm converged.	0,649	0,975
	Nodal status	0 positive nodes	267	14,7	82	30,7	282	15,5	74	26,2	1,25		Algorithm converged.	0,86	1,81	0,045		Algorithm converged.	-0,031	0,120	1,170		Algorithm converged.	0,897	1,527	0,2464	0,6060	0,854		Algorithm converged.	0,655	1,115
		>= 1 positive nodes	1271	70,2	348	27,4	1309	71,8	331	25,3	1,11		Algorithm converged.	0,93	1,33	0,021		Algorithm converged.	-0,013	0,055	1,083		Algorithm converged.	0,952	1,232	0,2275		0,924		Algorithm converged.	0,812	1,051
	Menopausal status at randomization	Premenopausal	754	41,6	218	28,9	793	43,5	216	27,2	1,09		Algorithm converged.	0,87	1,36	0,017		Algorithm converged.	-0,028	0,062	1,061		Algorithm converged.	0,905	1,245	0,4638	0,5921	0,942		Algorithm converged.	0,803	1,105
		Postmenopausal	780	43,1	210	26,9	790	43,3	188	23,8	1,18		Algorithm converged.	0,94	1,48	0,031		Algorithm converged.	-0,012	0,074	1,131		Algorithm converged.	0,954	1,341	0,1551		0,884		Algorithm converged.	0,746	1,048
		Unknown/Missing	4	0,2	2	50,0	8	0,4	1	12,5	7,00		Algorithm converged.	0,40	123,35	0,375		Algorithm converged.	-0,166	0,916	4,000		Algorithm converged.	0,500	31,981	0,1912		0,250		Algorithm converged.	0,031	1,999
	Age II	< 65	1358	75,0	378	27,8	1416	77,7	362	25,6	1,12		Algorithm converged.	0,95	1,33	0,023		Algorithm converged.	-0,010	0,056	1,089		Algorithm converged.	0,962	1,232	0,1767	0,6817	0,918		Algorithm converged.	0,812	1,039
		>= 65	180	9,9	52	28,9	175	9,6	43	24,6	1,25		Algorithm converged.	0,78	2,00	0,043		Algorithm converged.	-0,049	0,135	1,176		Algorithm converged.	0,832	1,662	0,3596		0,851		Algorithm converged.	0,602	1,203

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	7	25,9	22	1,2	8	36,4	0,61		Algorithm converged.	0,18	2,08	-0,104		Algorithm converged.	-0,365	0,156	0,713		Algorithm converged.	0,307	1,658	0,4320	0,5793	1,403		Algorithm converged.	0,603	3,261
		Grade 2	473	26,1	126	26,6	486	26,7	115	23,7	1,17		Algorithm converged.	0,87	1,57	0,030		Algorithm converged.	-0,025	0,085	1,126		Algorithm converged.	0,905	1,401	0,2886		0,888		Algorithm converged.	0,714	1,106
		Grade 3	979	54,1	281	28,7	1024	56,2	262	25,6	1,17		Algorithm converged.	0,96	1,43	0,031		Algorithm converged.	-0,008	0,070	1,122		Algorithm converged.	0,972	1,295	0,1170		0,891		Algorithm converged.	0,772	1,029
		Unevaluable/Unknown/Missing	59	3,3	16	27,1	59	3,2	20	33,9	0,73		Algorithm converged.	0,33	1,59	-0,068		Algorithm converged.	-0,234	0,098	0,800		Algorithm converged.	0,462	1,386	0,4261		1,250		Algorithm converged.	0,722	2,165
	Type of surgery for primary tumor	Breast conserving surgery	608	33,6	176	28,9	600	32,9	167	27,8	1,06		Algorithm converged.	0,82	1,36	0,011		Algorithm converged.	-0,040	0,062	1,040		Algorithm converged.	0,869	1,244	0,6677	0,4411	0,962		Algorithm converged.	0,804	1,150
		Mastectomy	930	51,4	254	27,3	990	54,3	237	23,9	1,19		Algorithm converged.	0,97	1,47	0,034		Algorithm converged.	-0,005	0,073	1,141		Algorithm converged.	0,979	1,329	0,0907		0,877		Algorithm converged.	0,752	1,021
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	568	31,4	188	33,1	579	31,8	142	24,5	1,52		Algorithm converged.	1,18	1,97	0,086		Algorithm converged.	0,034	0,138	1,350		Algorithm converged.	1,122	1,623	0,0015	0,0210	0,741		Algorithm converged.	0,616	0,891
		>= 2 - < 5 cm	845	46,7	205	24,3	861	47,2	217	25,2	0,95		Algorithm converged.	0,76	1,18	-0,009		Algorithm converged.	-0,050	0,032	0,963		Algorithm converged.	0,816	1,136	0,6518		1,039		Algorithm converged.	0,880	1,226
		>= 5 cm	123	6,8	36	29,3	149	8,2	45	30,2	0,96		Algorithm converged.	0,57	1,61	-0,009		Algorithm converged.	-0,118	0,100	0,969		Algorithm converged.	0,671	1,400	0,8671		1,032		Algorithm converged.	0,715	1,490
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1190	65,7	339	28,5	1201	65,9	315	26,2	1,12		Algorithm converged.	0,94	1,34	0,023		Algorithm converged.	-0,013	0,058	1,086		Algorithm converged.	0,953	1,238	0,2155	0,7706	0,921		Algorithm converged.	0,808	1,049
		No	348	19,2	91	26,1	390	21,4	90	23,1	1,18		Algorithm converged.	0,84	1,65	0,031		Algorithm converged.	-0,032	0,093	1,133		Algorithm converged.	0,880	1,459	0,3329		0,883		Algorithm converged.	0,685	1,137
	Race	White	1017	56,2	301	29,6	1056	57,9	274	25,9	1,20		Algorithm converged.	0,99	1,45	0,036		Algorithm converged.	-0,002	0,075	1,141		Algorithm converged.	0,992	1,311	0,0638	0,6525	0,877		Algorithm converged.	0,763	1,008

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	6	28,6	27	1,5	5	18,5	1,76		Algorithm converged.	0,45	6,83	0,101		Algorithm converged.	-0,142	0,343	1,543		Algorithm converged.	0,545	4,369	0,4142		0,648		Algorithm converged.	0,229	1,835
		Asian	449	24,8	111	24,7	460	25,2	114	24,8	1,00		Algorithm converged.	0,74	1,35	-0,001		Algorithm converged.	-0,057	0,056	0,998		Algorithm converged.	0,795	1,251	0,9830		1,002		Algorithm converged.	0,799	1,258
		Other	47	2,6	10	21,3	47	2,6	11	23,4	0,88		Algorithm converged.	0,33	2,34	-0,021		Algorithm converged.	-0,190	0,147	0,909		Algorithm converged.	0,427	1,934	0,8046		1,100		Algorithm converged.	0,517	2,340
		Missing	4	0,2	2	50,0	1	<0.1	1	100,0	0,00		Algorithm converged.	0,00	0,00	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
FU MONTH 36	All	n/a	1362	75,2	318	23,3	1322	72,5	333	25,2	0,90		Algorithm converged.	0,76	1,08	-0,018		Algorithm converged.	-0,051	0,014	0,927		Algorithm converged.	0,811	1,060	0,2660		1,079		Algorithm converged.	0,944	1,233
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	9	20,5	34	1,9	4	11,8	1,93		Algorithm converged.	0,54	6,90	0,087		Algorithm converged.	-0,074	0,248	1,739		Algorithm converged.	0,585	5,168	0,3197	0,1859	0,575		Algorithm converged.	0,193	1,710
		0 positive nodes, tumor > 1 cm	213	11,8	41	19,2	222	12,2	58	26,1	0,67		Algorithm converged.	0,43	1,06	-0,069		Algorithm converged.	-0,147	0,010	0,737		Algorithm converged.	0,518	1,049	0,0898		1,357		Algorithm converged.	0,954	1,932
		1-3 positive nodes	693	38,3	179	25,8	654	35,9	165	25,2	1,03		Algorithm converged.	0,81	1,32	0,006		Algorithm converged.	-0,041	0,053	1,024		Algorithm converged.	0,853	1,229	0,8007		0,977		Algorithm converged.	0,814	1,172
		>= 4 positive nodes	412	22,7	89	21,6	412	22,6	106	25,7	0,80		Algorithm converged.	0,58	1,10	-0,041		Algorithm converged.	-0,099	0,017	0,840		Algorithm converged.	0,656	1,074	0,1645		1,191		Algorithm converged.	0,931	1,524
	Adjuvant chemotherapy regimen	Anthracycline	1087	60,0	242	22,3	1062	58,3	271	25,5	0,84		Algorithm converged.	0,69	1,02	-0,033		Algorithm converged.	-0,069	0,003	0,872		Algorithm converged.	0,750	1,015	0,0772	0,0872	1,146		Algorithm converged.	0,985	1,333

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	275	15,2	76	27,6	260	14,3	62	23,8	1,22		Algorithm converged.	0,83	1,80	0,038		Algorithm converged.	-0,036	0,112	1,159		Algorithm converged.	0,868	1,548	0,3178		0,863		Algorithm converged.	0,646	1,152
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	142	21,4	641	35,2	159	24,8	0,82		Algorithm converged.	0,64	1,07	-0,035		Algorithm converged.	-0,080	0,011	0,861		Algorithm converged.	0,706	1,050	0,1392	0,3137	1,162		Algorithm converged.	0,952	1,417
		Positive (ER and/or PgR positive)	697	38,5	176	25,3	681	37,4	174	25,6	0,98		Algorithm converged.	0,77	1,25	-0,003		Algorithm converged.	-0,049	0,043	0,988		Algorithm converged.	0,825	1,184	0,8984		1,012		Algorithm converged.	0,844	1,213
	Geographical region II	USA/Canada	179	9,9	39	21,8	154	8,4	38	24,7	0,85		Algorithm converged.	0,51	1,42	-0,029		Algorithm converged.	-0,120	0,062	0,883		Algorithm converged.	0,597	1,306	0,5331	-	1,133		Algorithm converged.	0,766	1,675
		Western Europe	587	32,4	151	25,7	574	31,5	157	27,4	0,92		Algorithm converged.	0,71	1,19	-0,016		Algorithm converged.	-0,067	0,035	0,940		Algorithm converged.	0,777	1,139	0,5300		1,063		Algorithm converged.	0,878	1,288
		Asia Pacific	415	22,9	89	21,4	428	23,5	96	22,4	0,94		Algorithm converged.	0,68	1,31	-0,010		Algorithm converged.	-0,066	0,046	0,956		Algorithm converged.	0,741	1,234	0,7300		1,046		Algorithm converged.	0,811	1,349
		Latin America	34	1,9	2	5,9	36	2,0	6	16,7	0,31		Algorithm converged.	0,06	1,67	-0,108		Algorithm converged.	-0,253	0,037	0,353		Algorithm converged.	0,076	1,630	0,1822		2,833		Algorithm converged.	0,613	13,086
		Other	147	8,1	37	25,2	130	7,1	36	27,7	0,88		Algorithm converged.	0,51	1,50	-0,025		Algorithm converged.	-0,129	0,079	0,909		Algorithm converged.	0,613	1,347	0,6343		1,100		Algorithm converged.	0,742	1,631
	Protocol version	Protocol A	958	52,9	220	23,0	916	50,2	222	24,2	0,93		Algorithm converged.	0,75	1,15	-0,013		Algorithm converged.	-0,051	0,026	0,948		Algorithm converged.	0,805	1,115	0,5170	0,6514	1,055		Algorithm converged.	0,897	1,242
		Protocol amendment B	404	22,3	98	24,3	406	22,3	111	27,3	0,85		Algorithm converged.	0,62	1,17	-0,031		Algorithm converged.	-0,091	0,029	0,887		Algorithm converged.	0,702	1,121	0,3167		1,127		Algorithm converged.	0,892	1,424
	Nodal status	0 positive nodes	257	14,2	50	19,5	256	14,0	62	24,2	0,76		Algorithm converged.	0,50	1,15	-0,048		Algorithm converged.	-0,119	0,024	0,803		Algorithm converged.	0,578	1,117	0,1932	0,3491	1,245		Algorithm converged.	0,895	1,731
		>= 1 positive nodes	1105	61,0	268	24,3	1066	58,5	271	25,4	0,94		Algorithm converged.	0,77	1,14	-0,012		Algorithm converged.	-0,048	0,025	0,954		Algorithm converged.	0,824	1,104	0,5286		1,048		Algorithm converged.	0,905	1,213
	Menopausal status at randomization	Premenopausal	663	36,6	162	24,4	657	36,0	156	23,7	1,04		Algorithm converged.	0,81	1,34	0,007		Algorithm converged.	-0,039	0,053	1,029		Algorithm converged.	0,850	1,246	0,7694	0,1370	0,972		Algorithm converged.	0,802	1,177

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	695	38,4	154	22,2	659	36,1	174	26,4	0,79		Algorithm converged.	0,62	1,02	-0,042		Algorithm converged.	-0,088	0,003	0,839		Algorithm converged.	0,695	1,014	0,0689		1,192		Algorithm converged.	0,987	1,439
		Unknown/Missing	4	0,2	2	50,0	6	0,3	3	50,0	1,00		Algorithm converged.	0,08	12,56	0,000		Algorithm converged.	-0,633	0,633	1,000		Algorithm converged.	0,282	3,544	1,0000		1,000		Algorithm converged.	0,282	3,544
	Age II	< 65	1209	66,8	284	23,5	1181	64,8	295	25,0	0,92		Algorithm converged.	0,76	1,11	-0,015		Algorithm converged.	-0,049	0,019	0,940		Algorithm converged.	0,816	1,084	0,3959	0,5452	1,063		Algorithm converged.	0,923	1,225
		>= 65	153	8,4	34	22,2	141	7,7	38	27,0	0,77		Algorithm converged.	0,45	1,32	-0,047		Algorithm converged.	-0,146	0,051	0,825		Algorithm converged.	0,552	1,233	0,3471		1,213		Algorithm converged.	0,811	1,813
	Histological grade	Grade 1	26	1,4	8	30,8	20	1,1	6	30,0	1,04		Algorithm converged.	0,29	3,69	0,008		Algorithm converged.	-0,260	0,276	1,026		Algorithm converged.	0,424	2,481	0,9552	0,4093	0,975		Algorithm converged.	0,403	2,359
		Grade 2	428	23,6	110	25,7	405	22,2	96	23,7	1,11		Algorithm converged.	0,81	1,53	0,020		Algorithm converged.	-0,039	0,079	1,084		Algorithm converged.	0,855	1,375	0,5047		0,922		Algorithm converged.	0,727	1,170
		Grade 3	859	47,4	196	22,8	847	46,5	217	25,6	0,86		Algorithm converged.	0,69	1,07	-0,028		Algorithm converged.	-0,069	0,013	0,891		Algorithm converged.	0,753	1,054	0,1771		1,123		Algorithm converged.	0,949	1,329
		Unevaluable/Unknown/Missing	49	2,7	4	8,2	50	2,7	14	28,0	0,23		Algorithm converged.	0,07	0,75	-0,198		Algorithm converged.	-0,345	-0,052	0,292		Algorithm converged.	0,103	0,824	0,0201		3,430		Algorithm converged.	1,214	9,695
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	127	23,2	517	28,4	144	27,9	0,78		Algorithm converged.	0,59	1,03	-0,046		Algorithm converged.	-0,099	0,006	0,834		Algorithm converged.	0,678	1,024	0,0834	0,1920	1,200		Algorithm converged.	0,976	1,474
		Mastectomy	815	45,0	191	23,4	805	44,2	189	23,5	1,00		Algorithm converged.	0,79	1,26	0,000		Algorithm converged.	-0,042	0,041	0,998		Algorithm converged.	0,837	1,190	0,9838		1,002		Algorithm converged.	0,840	1,195
	Tumor size	0 - < 2 cm	516	28,5	125	24,2	489	26,8	130	26,6	0,88		Algorithm converged.	0,66	1,17	-0,024		Algorithm converged.	-0,077	0,030	0,911		Algorithm converged.	0,737	1,127	0,3903	0,9829	1,097		Algorithm converged.	0,888	1,357
		>= 2 - < 5 cm	744	41,1	171	23,0	717	39,3	178	24,8	0,90		Algorithm converged.	0,71	1,15	-0,018		Algorithm converged.	-0,062	0,025	0,926		Algorithm converged.	0,771	1,112	0,4093		1,080		Algorithm converged.	0,899	1,297
		>= 5 cm	100	5,5	21	21,0	114	6,3	25	21,9	0,95		Algorithm converged.	0,49	1,82	-0,009		Algorithm converged.	-0,119	0,101	0,958		Algorithm converged.	0,573	1,602	0,8689		1,044		Algorithm converged.	0,624	1,746

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	2	0,1	1	50,0	2	0,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Loco-regional radiotherapy	Yes	1041	57,5	248	23,8	1007	55,2	265	26,3	0,88		Algorithm converged.	0,72	1,07	-0,025		Algorithm converged.	-0,062	0,013		0,905		Algorithm converged.	0,779	1,052	0,1933	0,5165	1,105		Algorithm converged.	0,951	1,283
		No	321	17,7	70	21,8	315	17,3	68	21,6	1,01		Algorithm converged.	0,69	1,48	0,002		Algorithm converged.	-0,062	0,066		1,010		Algorithm converged.	0,752	1,357	0,9465		0,990		Algorithm converged.	0,737	1,330
	Race	White	895	49,4	221	24,7	874	47,9	237	27,1	0,88		Algorithm converged.	0,71	1,09	-0,024		Algorithm converged.	-0,065	0,017		0,911		Algorithm converged.	0,778	1,066	0,2448	-	1,098		Algorithm converged.	0,938	1,286
		Black	18	1,0	3	16,7	19	1,0	2	10,5	1,70		Algorithm converged.	0,25	11,59	0,061		Algorithm converged.	-0,159	0,282		1,583		Algorithm converged.	0,298	8,403	0,5894		0,632		Algorithm converged.	0,119	3,352
		Asian	400	22,1	89	22,3	395	21,7	89	22,5	0,98		Algorithm converged.	0,70	1,37	-0,003		Algorithm converged.	-0,061	0,055		0,988		Algorithm converged.	0,762	1,279	0,9241		1,013		Algorithm converged.	0,782	1,312
		Other	44	2,4	4	9,1	33	1,8	5	15,2	0,56		Algorithm converged.	0,14	2,27	-0,061		Algorithm converged.	-0,210	0,088		0,600		Algorithm converged.	0,175	2,063	0,4175		1,667		Algorithm converged.	0,485	5,730
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC05_W15_SG.xls
26OCT2020 16:13

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Appetite Loss Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO												PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk								Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	235	15,3	1594	87,4	180	11,3	1,42		Algorithm converged.	1,15	1,74	0,040		Algorithm converged.	0,016	0,064		1,353		Algorithm converged.	1,129	1,622	0,0011		0,739		Algorithm converged.	0,617	0,886
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	8	18,6	35	1,9	0	0,0	NE		Algorithm converged.	NE	NE	0,201	*	WARNING: The relative Hessian convergence criterion of 1.6947667457 is greater than the limit of 0.0001. The convergence is questionable.	-0,152	0,555		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	225	12,4	35	15,6	247	13,5	24	9,7	1,71		Algorithm converged.	0,98	2,98	0,058		Algorithm converged.	-0,002	0,118		1,601		Algorithm converged.	0,984	2,605	0,0583		0,625		Algorithm converged.	0,384	1,017
		1-3 positive nodes	769	42,5	109	14,2	796	43,7	86	10,8	1,36		Algorithm converged.	1,01	1,84	0,034		Algorithm converged.	0,001	0,066		1,312		Algorithm converged.	1,007	1,710	0,0444		0,762		Algorithm converged.	0,585	0,993
		>= 4 positive nodes	501	27,7	83	16,6	516	28,3	70	13,6	1,27		Algorithm converged.	0,90	1,79	0,030		Algorithm converged.	-0,014	0,074		1,221		Algorithm converged.	0,911	1,638	0,1818		0,819		Algorithm converged.	0,611	1,098
	Adjuvant chemotherapy regimen	Anthracycline	1230	67,9	179	14,6	1278	70,1	143	11,2	1,35		Algorithm converged.	1,07	1,71	0,034		Algorithm converged.	0,007	0,060		1,301		Algorithm converged.	1,059	1,597	0,0122	0,4234	0,769		Algorithm converged.	0,626	0,944

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	308	17,0	56	18,2	316	17,3	37	11,7	1,68		Algorithm converged.	1,07	2,62	0,065		Algorithm converged.	0,009	0,121	1,553		Algorithm converged.	1,057	2,281	0,0249		0,644		Algorithm converged.	0,438	0,946
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	748	41,3	109	14,6	752	41,3	84	11,2	1,36		Algorithm converged.	1,00	1,84	0,034		Algorithm converged.	0,000	0,068	1,305		Algorithm converged.	1,000	1,702	0,0501	0,7063	0,767		Algorithm converged.	0,588	1,000
		Positive (ER and/or PgR positive)	790	43,6	126	15,9	842	46,2	96	11,4	1,47		Algorithm converged.	1,11	1,96	0,045		Algorithm converged.	0,012	0,079	1,399		Algorithm converged.	1,093	1,791	0,0078		0,715		Algorithm converged.	0,558	0,915
	Geographical region II	USA/Canada	214	11,8	24	11,2	223	12,2	29	13,0	0,85		Algorithm converged.	0,47	1,50	-0,018		Algorithm converged.	-0,079	0,043	0,862		Algorithm converged.	0,519	1,432	0,5673	0,0904	1,160		Algorithm converged.	0,698	1,926
		Western Europe	663	36,6	113	17,0	678	37,2	66	9,7	1,91		Algorithm converged.	1,38	2,64	0,073		Algorithm converged.	0,037	0,109	1,751		Algorithm converged.	1,318	2,326	0,0001		0,571		Algorithm converged.	0,430	0,759
		Asia Pacific	461	25,5	64	13,9	488	26,8	61	12,5	1,13		Algorithm converged.	0,77	1,64	0,014		Algorithm converged.	-0,029	0,057	1,111		Algorithm converged.	0,801	1,540	0,5291		0,900		Algorithm converged.	0,649	1,248
		Latin America	38	2,1	11	28,9	42	2,3	7	16,7	2,04		Algorithm converged.	0,70	5,95	0,123		Algorithm converged.	-0,060	0,306	1,737		Algorithm converged.	0,750	4,023	0,1977		0,576		Algorithm converged.	0,249	1,334
		Other	162	8,9	23	14,2	163	8,9	17	10,4	1,42		Algorithm converged.	0,73	2,77	0,038		Algorithm converged.	-0,034	0,109	1,361		Algorithm converged.	0,756	2,451	0,3039		0,735		Algorithm converged.	0,408	1,323
	Protocol version	Protocol A	1051	58,0	158	15,0	1091	59,8	116	10,6	1,49		Algorithm converged.	1,15	1,92	0,044		Algorithm converged.	0,016	0,072	1,414		Algorithm converged.	1,130	1,769	0,0025	0,5062	0,707		Algorithm converged.	0,565	0,885
		Protocol amendment B	487	26,9	77	15,8	503	27,6	64	12,7	1,29		Algorithm converged.	0,90	1,84	0,031		Algorithm converged.	-0,013	0,074	1,243		Algorithm converged.	0,914	1,690	0,1658		0,805		Algorithm converged.	0,592	1,094
	Nodal status	0 positive nodes	268	14,8	43	16,0	282	15,5	24	8,5	2,05		Algorithm converged.	1,21	3,49	0,075		Algorithm converged.	0,021	0,130	1,885		Algorithm converged.	1,178	3,018	0,0083	0,1247	0,530		Algorithm converged.	0,331	0,849
		>= 1 positive nodes	1270	70,1	192	15,1	1312	72,0	156	11,9	1,32		Algorithm converged.	1,05	1,66	0,032		Algorithm converged.	0,006	0,059	1,271		Algorithm converged.	1,044	1,548	0,0167		0,786		Algorithm converged.	0,646	0,957
	Menopausal status at randomization	Premenopausal	753	41,6	94	12,5	799	43,8	88	11,0	1,15		Algorithm converged.	0,85	1,57	0,015		Algorithm converged.	-0,017	0,047	1,133		Algorithm converged.	0,863	1,489	0,3688	0,0969	0,882		Algorithm converged.	0,671	1,159

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	781	43,1	141	18,1	787	43,2	92	11,7	1,66		Algorithm converged.	1,25	2,21	0,064		Algorithm converged.	0,029	0,099	1,544		Algorithm converged.	1,211	1,970	0,0005		0,648		Algorithm converged.	0,508	0,826
		Unknown/Missing	4	0,2	0	0,0	8	0,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	1358	75,0	192	14,1	1419	77,8	165	11,6	1,25		Algorithm converged.	1,00	1,56	0,025		Algorithm converged.	0,000	0,050	1,216		Algorithm converged.	1,001	1,477	0,0486	0,0031	0,822		Algorithm converged.	0,677	0,999
		>= 65	180	9,9	43	23,9	175	9,6	15	8,6	3,35		Algorithm converged.	1,78	6,29	0,153		Algorithm converged.	0,078	0,228	2,787		Algorithm converged.	1,609	4,829	0,0003		0,359		Algorithm converged.	0,207	0,622
	Histological grade	Grade 1	27	1,5	3	11,1	22	1,2	5	22,7	0,43		Algorithm converged.	0,09	2,02	-0,116		Algorithm converged.	-0,328	0,095	0,489		Algorithm converged.	0,131	1,823	0,2865	-	2,045		Algorithm converged.	0,549	7,627
		Grade 2	472	26,1	82	17,4	487	26,7	57	11,7	1,59		Algorithm converged.	1,10	2,28	0,057		Algorithm converged.	0,012	0,101	1,484		Algorithm converged.	1,085	2,031	0,0135		0,674		Algorithm converged.	0,492	0,922
		Grade 3	980	54,1	144	14,7	1026	56,3	112	10,9	1,41		Algorithm converged.	1,08	1,83	0,038		Algorithm converged.	0,009	0,067	1,346		Algorithm converged.	1,069	1,696	0,0116		0,743		Algorithm converged.	0,590	0,936
		Unevaluable/Unknown/Missing	59	3,3	6	10,2	59	3,2	6	10,2	1,00		Algorithm converged.	0,30	3,30	0,000		Algorithm converged.	-0,109	0,109	1,000		Algorithm converged.	0,342	2,923	1,0000		1,000		Algorithm converged.	0,342	2,923
	Type of surgery for primary tumor	Breast conserving surgery	607	33,5	102	16,8	600	32,9	54	9,0	2,04		Algorithm converged.	1,44	2,90	0,078		Algorithm converged.	0,041	0,116	1,867		Algorithm converged.	1,369	2,546	<.0001	0,0090	0,536		Algorithm converged.	0,393	0,730
		Mastectomy	931	51,4	133	14,3	993	54,5	126	12,7	1,15		Algorithm converged.	0,88	1,49	0,016		Algorithm converged.	-0,015	0,047	1,126		Algorithm converged.	0,898	1,412	0,3054		0,888		Algorithm converged.	0,708	1,114
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	566	31,3	87	15,4	581	31,9	59	10,2	1,61		Algorithm converged.	1,13	2,29	0,052		Algorithm converged.	0,014	0,091	1,514		Algorithm converged.	1,111	2,063	0,0087	0,0429	0,661		Algorithm converged.	0,485	0,900
		>= 2 - < 5 cm	847	46,8	130	15,3	862	47,3	91	10,6	1,54		Algorithm converged.	1,15	2,05	0,048		Algorithm converged.	0,016	0,080	1,454		Algorithm converged.	1,132	1,868	0,0034		0,688		Algorithm converged.	0,535	0,884
		>= 5 cm	123	6,8	18	14,6	149	8,2	30	20,1	0,68		Algorithm converged.	0,36	1,29	-0,055		Algorithm converged.	-0,145	0,035	0,727		Algorithm converged.	0,426	1,239	0,2410		1,376		Algorithm converged.	0,807	2,345
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1189	65,7	183	15,4	1204	66,0	139	11,5	1,39		Algorithm converged.	1,10	1,77	0,038		Algorithm converged.	0,011	0,066	1,333		Algorithm converged.	1,086	1,637	0,0061	0,7824	0,750		Algorithm converged.	0,611	0,921
		No	349	19,3	52	14,9	390	21,4	41	10,5	1,49		Algorithm converged.	0,96	2,31	0,044		Algorithm converged.	-0,004	0,092	1,417		Algorithm converged.	0,966	2,079	0,0743		0,706		Algorithm converged.	0,481	1,035
	Race	White	1016	56,1	156	15,4	1059	58,1	111	10,5	1,55		Algorithm converged.	1,19	2,01	0,049		Algorithm converged.	0,020	0,078	1,465		Algorithm converged.	1,167	1,839	0,0010	-	0,683		Algorithm converged.	0,544	0,857
		Black	21	1,2	2	9,5	27	1,5	6	22,2	0,37		Algorithm converged.	0,07	2,05	-0,127		Algorithm converged.	-0,328	0,074	0,429		Algorithm converged.	0,096	1,912	0,2667		2,333		Algorithm converged.	0,523	10,408
		Asian	450	24,8	64	14,2	460	25,2	56	12,2	1,20		Algorithm converged.	0,81	1,76	0,020		Algorithm converged.	-0,023	0,064	1,168		Algorithm converged.	0,836	1,632	0,3619		0,856		Algorithm converged.	0,613	1,196
		Other	47	2,6	13	27,7	47	2,6	7	14,9	2,18		Algorithm converged.	0,78	6,10	0,128		Algorithm converged.	-0,036	0,291	1,857		Algorithm converged.	0,814	4,238	0,1414		0,538		Algorithm converged.	0,236	1,229
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1361	75,2	121	8,9	1326	72,7	125	9,4	0,94		Algorithm converged.	0,72	1,22	-0,005		Algorithm converged.	-0,027	0,016	0,943		Algorithm converged.	0,743	1,197	0,6299		1,060		Algorithm converged.	0,836	1,346
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	3	6,8	35	1,9	1	2,9	2,49		Algorithm converged.	0,25	25,02	0,040		Algorithm converged.	-0,053	0,132	2,386		Algorithm converged.	0,259	21,954	0,4424	-	0,419		Algorithm converged.	0,046	3,855
		0 positive nodes, tumor > 1 cm	212	11,7	14	6,6	221	12,1	18	8,1	0,80		Algorithm converged.	0,39	1,65	-0,015		Algorithm converged.	-0,065	0,034	0,811		Algorithm converged.	0,414	1,589	0,5410		1,233		Algorithm converged.	0,630	2,416
		1-3 positive nodes	693	38,3	61	8,8	656	36,0	54	8,2	1,08		Algorithm converged.	0,73	1,58	0,006		Algorithm converged.	-0,024	0,035	1,069		Algorithm converged.	0,753	1,518	0,7077		0,935		Algorithm converged.	0,659	1,327
		>= 4 positive nodes	412	22,7	43	10,4	414	22,7	52	12,6	0,81		Algorithm converged.	0,53	1,25	-0,021		Algorithm converged.	-0,065	0,022	0,831		Algorithm converged.	0,568	1,215	0,3398		1,203		Algorithm converged.	0,823	1,760
	Adjuvant chemotherapy regimen	Anthracycline	1087	60,0	96	8,8	1065	58,4	103	9,7	0,90		Algorithm converged.	0,68	1,21	-0,008		Algorithm converged.	-0,033	0,016	0,913		Algorithm converged.	0,701	1,190	0,5016	0,5832	1,095		Algorithm converged.	0,840	1,427

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	274	15,1	25	9,1	261	14,3	22	8,4	1,09		Algorithm converged.	0,60	1,99	0,007		Algorithm converged.	-0,041	0,055	1,082		Algorithm converged.	0,626	1,871	0,7766		0,924		Algorithm converged.	0,534	1,597
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	664	36,7	54	8,1	643	35,3	54	8,4	0,97		Algorithm converged.	0,65	1,43	-0,003		Algorithm converged.	-0,033	0,027	0,968		Algorithm converged.	0,675	1,390	0,8616	0,8507	1,033		Algorithm converged.	0,720	1,482
		Positive (ER and/or PgR positive)	697	38,5	67	9,6	683	37,5	71	10,4	0,92		Algorithm converged.	0,64	1,30	-0,008		Algorithm converged.	-0,039	0,024	0,925		Algorithm converged.	0,674	1,269	0,6281		1,081		Algorithm converged.	0,788	1,484
	Geographical region II	USA/Canada	179	9,9	17	9,5	155	8,5	7	4,5	2,22		Algorithm converged.	0,89	5,50	0,050		Algorithm converged.	-0,004	0,104	2,103		Algorithm converged.	0,896	4,938	0,0878	-	0,476		Algorithm converged.	0,203	1,116
		Western Europe	586	32,4	50	8,5	576	31,6	50	8,7	0,98		Algorithm converged.	0,65	1,48	-0,001		Algorithm converged.	-0,034	0,031	0,983		Algorithm converged.	0,676	1,430	0,9283		1,017		Algorithm converged.	0,699	1,480
		Asia Pacific	415	22,9	42	10,1	428	23,5	46	10,7	0,94		Algorithm converged.	0,60	1,45	-0,006		Algorithm converged.	-0,048	0,035	0,942		Algorithm converged.	0,634	1,399	0,7660		1,062		Algorithm converged.	0,715	1,578
		Latin America	34	1,9	2	5,9	36	2,0	3	8,3	0,69		Algorithm converged.	0,11	4,39	-0,025		Algorithm converged.	-0,145	0,096	0,706		Algorithm converged.	0,126	3,969	0,6926		1,417		Algorithm converged.	0,252	7,965
		Other	147	8,1	10	6,8	131	7,2	19	14,5	0,43		Algorithm converged.	0,19	0,96	-0,077		Algorithm converged.	-0,150	-0,004	0,469		Algorithm converged.	0,226	0,972	0,0417		2,132		Algorithm converged.	1,029	4,418
	Protocol version	Protocol A	956	52,8	78	8,2	917	50,3	81	8,8	0,92		Algorithm converged.	0,66	1,27	-0,007		Algorithm converged.	-0,032	0,019	0,924		Algorithm converged.	0,686	1,244	0,6009	0,7936	1,083		Algorithm converged.	0,804	1,458
		Protocol amendment B	405	22,4	43	10,6	409	22,4	44	10,8	0,99		Algorithm converged.	0,63	1,54	-0,001		Algorithm converged.	-0,044	0,041	0,987		Algorithm converged.	0,663	1,468	0,9482		1,013		Algorithm converged.	0,681	1,507
	Nodal status	0 positive nodes	256	14,1	17	6,6	256	14,0	19	7,4	0,89		Algorithm converged.	0,45	1,75	-0,008		Algorithm converged.	-0,052	0,036	0,895		Algorithm converged.	0,476	1,682	0,7297	0,8629	1,118		Algorithm converged.	0,595	2,101
		>= 1 positive nodes	1105	61,0	104	9,4	1070	58,7	106	9,9	0,94		Algorithm converged.	0,71	1,26	-0,005		Algorithm converged.	-0,030	0,020	0,950		Algorithm converged.	0,735	1,229	0,6961		1,053		Algorithm converged.	0,814	1,361
	Menopausal status at randomization	Premenopausal	662	36,6	51	7,7	660	36,2	56	8,5	0,90		Algorithm converged.	0,61	1,34	-0,008		Algorithm converged.	-0,037	0,022	0,908		Algorithm converged.	0,631	1,306	0,6029	0,8092	1,101		Algorithm converged.	0,766	1,585

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	695	38,4	70	10,1	660	36,2	69	10,5	0,96		Algorithm converged.	0,68	1,36	-0,004		Algorithm converged.	-0,036	0,029	0,963		Algorithm converged.	0,703	1,320	0,8165		1,038		Algorithm converged.	0,758	1,422
		Unknown/Missing	4	0,2	0	0,0	6	0,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	1208	66,7	100	8,3	1185	65,0	113	9,5	0,86		Algorithm converged.	0,65	1,14	-0,013		Algorithm converged.	-0,035	0,010	0,868		Algorithm converged.	0,671	1,122	0,2805	0,0849	1,152		Algorithm converged.	0,891	1,489
		>= 65	153	8,4	21	13,7	141	7,7	12	8,5	1,71		Algorithm converged.	0,81	3,62	0,052		Algorithm converged.	-0,019	0,124	1,613		Algorithm converged.	0,824	3,156	0,1629		0,620		Algorithm converged.	0,317	1,213
	Histological grade	Grade 1	26	1,4	1	3,8	20	1,1	3	15,0	0,23		Algorithm converged.	0,02	2,37	-0,112		Algorithm converged.	-0,285	0,062	0,256		Algorithm converged.	0,029	2,284	0,2225	-	3,900		Algorithm converged.	0,438	34,736
		Grade 2	428	23,6	36	8,4	406	22,3	34	8,4	1,00		Algorithm converged.	0,62	1,64	0,000		Algorithm converged.	-0,037	0,038	1,004		Algorithm converged.	0,641	1,573	0,9847		0,996		Algorithm converged.	0,636	1,559
		Grade 3	858	47,4	81	9,4	849	46,6	83	9,8	0,96		Algorithm converged.	0,70	1,33	-0,003		Algorithm converged.	-0,031	0,025	0,966		Algorithm converged.	0,722	1,292	0,8140		1,036		Algorithm converged.	0,774	1,385
		Unevaluable/Unknown/Missing	49	2,7	3	6,1	51	2,8	5	9,8	0,60		Algorithm converged.	0,14	2,66	-0,037		Algorithm converged.	-0,142	0,069	0,624		Algorithm converged.	0,158	2,474	0,5026		1,601		Algorithm converged.	0,404	6,344
	Type of surgery for primary tumor	Breast conserving surgery	546	30,1	45	8,2	519	28,5	48	9,2	0,88		Algorithm converged.	0,58	1,35	-0,010		Algorithm converged.	-0,044	0,024	0,891		Algorithm converged.	0,604	1,314	0,5610	0,7129	1,122		Algorithm converged.	0,761	1,655
		Mastectomy	815	45,0	76	9,3	807	44,3	77	9,5	0,97		Algorithm converged.	0,70	1,36	-0,002		Algorithm converged.	-0,031	0,026	0,977		Algorithm converged.	0,723	1,321	0,8815		1,023		Algorithm converged.	0,757	1,383
	Tumor size	0 - < 2 cm	516	28,5	39	7,6	490	26,9	50	10,2	0,72		Algorithm converged.	0,46	1,12	-0,026		Algorithm converged.	-0,062	0,009	0,741		Algorithm converged.	0,496	1,105	0,1414	0,2928	1,350		Algorithm converged.	0,905	2,014
		>= 2 - < 5 cm	743	41,0	68	9,2	720	39,5	62	8,6	1,07		Algorithm converged.	0,75	1,53	0,005		Algorithm converged.	-0,024	0,035	1,063		Algorithm converged.	0,765	1,476	0,7163		0,941		Algorithm converged.	0,677	1,307
		>= 5 cm	100	5,5	14	14,0	114	6,3	13	11,4	1,26		Algorithm converged.	0,56	2,84	0,026		Algorithm converged.	-0,064	0,116	1,228		Algorithm converged.	0,606	2,486	0,5688		0,815		Algorithm converged.	0,402	1,649
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1040	57,4	98	9,4	1011	55,5	97	9,6	0,98		Algorithm converged.	0,73	1,32	-0,002		Algorithm converged.	-0,027	0,024	0,982		Algorithm converged.	0,752	1,283	0,8948	0,5128	1,018		Algorithm converged.	0,780	1,330
		No	321	17,7	23	7,2	315	17,3	28	8,9	0,79		Algorithm converged.	0,45	1,41	-0,017		Algorithm converged.	-0,059	0,025	0,806		Algorithm converged.	0,475	1,368	0,4246		1,241		Algorithm converged.	0,731	2,106
	Race	White	894	49,4	74	8,3	878	48,2	78	8,9	0,93		Algorithm converged.	0,66	1,29	-0,006		Algorithm converged.	-0,032	0,020	0,932		Algorithm converged.	0,687	1,263	0,6486	-	1,073		Algorithm converged.	0,792	1,455
		Black	18	1,0	2	11,1	19	1,0	2	10,5	1,06		Algorithm converged.	0,13	8,47	0,006		Algorithm converged.	-0,194	0,206	1,056		Algorithm converged.	0,166	6,719	0,9543		0,947		Algorithm converged.	0,149	6,031
		Asian	400	22,1	41	10,3	395	21,7	42	10,6	0,96		Algorithm converged.	0,61	1,51	-0,004		Algorithm converged.	-0,046	0,039	0,964		Algorithm converged.	0,642	1,449	0,8599		1,037		Algorithm converged.	0,690	1,559
		Other	44	2,4	4	9,1	33	1,8	3	9,1	1,00		Algorithm converged.	0,21	4,81	0,000		Algorithm converged.	-0,130	0,130	1,000		Algorithm converged.	0,240	4,167	1,0000		1,000		Algorithm converged.	0,240	4,167
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC06_W15_SG.xls
26OCT2020 16:16

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Constipation Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1538	84,9	202	13,1	1593	87,4	248	15,6	0,82		Algorithm converged.	0,67	1,00	-0,024		Algorithm converged.	-0,049	0,000	0,844		Algorithm converged.	0,710	1,002	0,0527		1,185		Algorithm converged.	0,998	1,408
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	5	11,6	35	1,9	6	17,1	0,64		Algorithm converged.	0,18	2,29	-0,055		Algorithm converged.	-0,213	0,102	0,678		Algorithm converged.	0,226	2,037	0,4891	0,7637	1,474		Algorithm converged.	0,491	4,428
		0 positive nodes, tumor > 1 cm	224	12,4	29	12,9	248	13,6	39	15,7	0,80		Algorithm converged.	0,47	1,34	-0,028		Algorithm converged.	-0,091	0,035	0,823		Algorithm converged.	0,527	1,285	0,3920		1,215		Algorithm converged.	0,778	1,896
		1-3 positive nodes	769	42,5	111	14,4	794	43,6	125	15,7	0,90		Algorithm converged.	0,68	1,19	-0,013		Algorithm converged.	-0,049	0,022	0,917		Algorithm converged.	0,724	1,160	0,4703		1,091		Algorithm converged.	0,862	1,380
		>= 4 positive nodes	502	27,7	57	11,4	516	28,3	78	15,1	0,72		Algorithm converged.	0,50	1,04	-0,038		Algorithm converged.	-0,079	0,004	0,751		Algorithm converged.	0,546	1,033	0,0784		1,331		Algorithm converged.	0,968	1,831
	Adjuvant chemotherapy regimen	Anthracycline	1231	68,0	167	13,6	1276	70,0	207	16,2	0,81		Algorithm converged.	0,65	1,01	-0,027		Algorithm converged.	-0,054	0,001	0,836		Algorithm converged.	0,693	1,009	0,0626	0,8237	1,196		Algorithm converged.	0,991	1,443
		Non-anthracycline	307	17,0	35	11,4	317	17,4	41	12,9	0,87		Algorithm converged.	0,54	1,40	-0,015		Algorithm converged.	-0,067	0,036	0,881		Algorithm converged.	0,578	1,345	0,5587		1,134		Algorithm converged.	0,743	1,732
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	749	41,4	103	13,8	751	41,2	113	15,0	0,90		Algorithm converged.	0,67	1,20	-0,013		Algorithm converged.	-0,048	0,023	0,914		Algorithm converged.	0,714	1,170	0,4753	0,3775	1,094		Algorithm converged.	0,855	1,401
		Positive (ER and/or PgR positive)	789	43,6	99	12,5	842	46,2	135	16,0	0,75		Algorithm converged.	0,57	0,99	-0,035		Algorithm converged.	-0,069	-0,001	0,783		Algorithm converged.	0,615	0,995	0,0457		1,278		Algorithm converged.	1,005	1,625

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	215	11,9	27	12,6	223	12,2	38	17,0	0,70		Algorithm converged.	0,41	1,19	-0,045		Algorithm converged.	-0,111	0,021	0,737		Algorithm converged.	0,467	1,163	0,1899	-	1,357		Algorithm converged.	0,860	2,142
		Western Europe	662	36,6	97	14,7	677	37,1	119	17,6	0,81		Algorithm converged.	0,60	1,08	-0,029		Algorithm converged.	-0,069	0,010	0,834		Algorithm converged.	0,652	1,066	0,1467		1,200		Algorithm converged.	0,938	1,534
		Asia Pacific	461	25,5	61	13,2	488	26,8	56	11,5	1,18		Algorithm converged.	0,80	1,73	0,018		Algorithm converged.	-0,024	0,059	1,153		Algorithm converged.	0,821	1,619	0,4111		0,867		Algorithm converged.	0,617	1,218
		Latin America	38	2,1	1	2,6	42	2,3	6	14,3	0,16		Algorithm converged.	0,02	1,41	-0,117		Algorithm converged.	-0,234	0,001	0,184		Algorithm converged.	0,023	1,461	0,1094		5,429		Algorithm converged.	0,684	43,065
		Other	162	8,9	16	9,9	163	8,9	29	17,8	0,51		Algorithm converged.	0,26	0,97	-0,079		Algorithm converged.	-0,154	-0,005	0,555		Algorithm converged.	0,314	0,982	0,0431		1,801		Algorithm converged.	1,018	3,186
	Protocol version	Protocol A	1050	58,0	137	13,0	1088	59,7	173	15,9	0,79		Algorithm converged.	0,62	1,01	-0,029		Algorithm converged.	-0,058	0,001	0,821		Algorithm converged.	0,667	1,010	0,0618	0,6391	1,219		Algorithm converged.	0,990	1,500
		Protocol amendment B	488	26,9	65	13,3	505	27,7	75	14,9	0,88		Algorithm converged.	0,62	1,26	-0,015		Algorithm converged.	-0,059	0,028	0,897		Algorithm converged.	0,659	1,220	0,4884		1,115		Algorithm converged.	0,819	1,517
	Nodal status	0 positive nodes	267	14,7	34	12,7	283	15,5	45	15,9	0,77		Algorithm converged.	0,48	1,25	-0,032		Algorithm converged.	-0,090	0,027	0,801		Algorithm converged.	0,530	1,210	0,2916	0,7852	1,249		Algorithm converged.	0,826	1,887
		>= 1 positive nodes	1271	70,2	168	13,2	1310	71,9	203	15,5	0,83		Algorithm converged.	0,67	1,04	-0,023		Algorithm converged.	-0,050	0,004	0,853		Algorithm converged.	0,706	1,031	0,0997		1,172		Algorithm converged.	0,970	1,417
	Menopausal status at randomization	Premenopausal	751	41,5	95	12,6	797	43,7	132	16,6	0,73		Algorithm converged.	0,55	0,97	-0,039		Algorithm converged.	-0,074	-0,004	0,764		Algorithm converged.	0,598	0,975	0,0305	0,2276	1,309		Algorithm converged.	1,026	1,671
		Postmenopausal	783	43,2	107	13,7	788	43,2	114	14,5	0,94		Algorithm converged.	0,70	1,24	-0,008		Algorithm converged.	-0,042	0,026	0,945		Algorithm converged.	0,740	1,206	0,6478		1,059		Algorithm converged.	0,829	1,352

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	8	0,4	2	25,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1357	74,9	172	12,7	1418	77,8	216	15,2	0,81		Algorithm converged.	0,65	1,00	-0,026		Algorithm converged.	-0,051	0,000	0,832		Algorithm converged.	0,691	1,002	0,0527	0,7320	1,202		Algorithm converged.	0,998	1,447
		>= 65	181	10,0	30	16,6	175	9,6	32	18,3	0,89		Algorithm converged.	0,51	1,54	-0,017		Algorithm converged.	-0,096	0,062	0,906		Algorithm converged.	0,576	1,425	0,6706		1,103		Algorithm converged.	0,702	1,735
	Histological grade	Grade 1	27	1,5	4	14,8	22	1,2	5	22,7	0,59		Algorithm converged.	0,14	2,54	-0,079		Algorithm converged.	-0,300	0,141	0,652		Algorithm converged.	0,199	2,139	0,4802	-	1,534		Algorithm converged.	0,468	5,033
		Grade 2	473	26,1	62	13,1	487	26,7	76	15,6	0,82		Algorithm converged.	0,57	1,17	-0,025		Algorithm converged.	-0,069	0,019	0,840		Algorithm converged.	0,616	1,146	0,2711		1,191		Algorithm converged.	0,873	1,624
		Grade 3	979	54,1	130	13,3	1025	56,2	155	15,1	0,86		Algorithm converged.	0,67	1,11	-0,018		Algorithm converged.	-0,049	0,012	0,878		Algorithm converged.	0,708	1,090	0,2383		1,139		Algorithm converged.	0,918	1,413
		Unevaluable/Unknown/Missing	59	3,3	6	10,2	59	3,2	12	20,3	0,44		Algorithm converged.	0,15	1,27	-0,102		Algorithm converged.	-0,230	0,027	0,500		Algorithm converged.	0,201	1,244	0,1359		2,000		Algorithm converged.	0,804	4,974
	Type of surgery for primary tumor	Breast conserving surgery	608	33,6	83	13,7	601	33,0	103	17,1	0,76		Algorithm converged.	0,56	1,05	-0,035		Algorithm converged.	-0,076	0,006	0,797		Algorithm converged.	0,610	1,040	0,0940	0,5731	1,255		Algorithm converged.	0,962	1,638
		Mastectomy	930	51,4	119	12,8	991	54,4	144	14,5	0,86		Algorithm converged.	0,66	1,12	-0,017		Algorithm converged.	-0,048	0,013	0,881		Algorithm converged.	0,703	1,104	0,2695		1,136		Algorithm converged.	0,906	1,423
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	567	31,3	81	14,3	581	31,9	97	16,7	0,83		Algorithm converged.	0,60	1,15	-0,024		Algorithm converged.	-0,066	0,018	0,856		Algorithm converged.	0,652	1,122	0,2603	0,9957	1,169		Algorithm converged.	0,891	1,533

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	846	46,7	105	12,4	861	47,2	127	14,8	0,82		Algorithm converged.	0,62	1,08	-0,023		Algorithm converged.	-0,056	0,009	0,841		Algorithm converged.	0,662	1,070	0,1594		1,188		Algorithm converged.	0,934	1,512
		>= 5 cm	123	6,8	16	13,0	149	8,2	23	15,4	0,82		Algorithm converged.	0,41	1,63	-0,024		Algorithm converged.	-0,107	0,059	0,843		Algorithm converged.	0,466	1,523	0,5708		1,187		Algorithm converged.	0,657	2,144
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1190	65,7	159	13,4	1203	66,0	183	15,2	0,86		Algorithm converged.	0,68	1,08	-0,019		Algorithm converged.	-0,047	0,010	0,878		Algorithm converged.	0,721	1,069	0,1964	0,4133	1,139		Algorithm converged.	0,935	1,386
		No	348	19,2	43	12,4	390	21,4	65	16,7	0,70		Algorithm converged.	0,47	1,07	-0,043		Algorithm converged.	-0,094	0,008	0,741		Algorithm converged.	0,519	1,060	0,1005		1,349		Algorithm converged.	0,944	1,928
	Race	White	1016	56,1	130	12,8	1058	58,0	176	16,6	0,74		Algorithm converged.	0,58	0,94	-0,038		Algorithm converged.	-0,069	-0,008	0,769		Algorithm converged.	0,624	0,949	0,0142	0,0316	1,300		Algorithm converged.	1,054	1,603
		Black	21	1,2	8	38,1	27	1,5	7	25,9	1,76		Algorithm converged.	0,51	6,02	0,122		Algorithm converged.	-0,144	0,387	1,469		Algorithm converged.	0,635	3,400	0,3686		0,681		Algorithm converged.	0,294	1,575
		Asian	450	24,8	60	13,3	460	25,2	56	12,2	1,11		Algorithm converged.	0,75	1,64	0,012		Algorithm converged.	-0,032	0,055	1,095		Algorithm converged.	0,779	1,539	0,6002		0,913		Algorithm converged.	0,650	1,283
		Other	47	2,6	2	4,3	47	2,6	9	19,1	0,19		Algorithm converged.	0,04	0,92	-0,149		Algorithm converged.	-0,275	-0,023	0,222		Algorithm converged.	0,051	0,974	0,0461		4,500		Algorithm converged.	1,027	19,726

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	4	0,2	2	50,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
FU MONTH 36	All	n/a	1363	75,3	219	16,1	1321	72,5	201	15,2	1,07		Algorithm converged.	0,87	1,31	0,009		Algorithm converged.	-0,019	0,036	1,056		Algorithm converged.	0,886	1,259	0,5438		0,947		Algorithm converged.	0,794	1,129
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	9	20,5	35	1,9	3	8,6	2,74		Algorithm converged.	0,68	11,03	0,119		Algorithm converged.	-0,032	0,270	2,386		Algorithm converged.	0,698	8,156	0,1654	0,1465	0,419		Algorithm converged.	0,123	1,432
		0 positive nodes, tumor > 1 cm	213	11,8	30	14,1	222	12,2	38	17,1	0,79		Algorithm converged.	0,47	1,34	-0,030		Algorithm converged.	-0,098	0,038	0,823		Algorithm converged.	0,530	1,278	0,3853		1,215		Algorithm converged.	0,783	1,887
		1-3 positive nodes	694	38,3	124	17,9	653	35,8	97	14,9	1,25		Algorithm converged.	0,93	1,67	0,030		Algorithm converged.	-0,009	0,070	1,203		Algorithm converged.	0,943	1,534	0,1367		0,831		Algorithm converged.	0,652	1,060
		>= 4 positive nodes	412	22,7	56	13,6	411	22,5	63	15,3	0,87		Algorithm converged.	0,59	1,28	-0,017		Algorithm converged.	-0,065	0,031	0,887		Algorithm converged.	0,636	1,237	0,4793		1,128		Algorithm converged.	0,808	1,573
	Adjuvant chemotherapy regimen	Anthracycline	1088	60,1	181	16,6	1061	58,2	164	15,5	1,09		Algorithm converged.	0,87	1,37	0,012		Algorithm converged.	-0,019	0,043	1,076		Algorithm converged.	0,887	1,306	0,4569	0,6627	0,929		Algorithm converged.	0,766	1,128
		Non-anthracycline	275	15,2	38	13,8	260	14,3	37	14,2	0,97		Algorithm converged.	0,59	1,57	-0,004		Algorithm converged.	-0,063	0,055	0,971		Algorithm converged.	0,638	1,477	0,8907		1,030		Algorithm converged.	0,677	1,567
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	105	15,8	641	35,2	94	14,7	1,09		Algorithm converged.	0,81	1,48	0,011		Algorithm converged.	-0,028	0,050	1,077		Algorithm converged.	0,833	1,391	0,5719	0,8384	0,929		Algorithm converged.	0,719	1,200

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	698	38,5	114	16,3	680	37,3	107	15,7	1,05		Algorithm converged.	0,78	1,39	0,006		Algorithm converged.	-0,033	0,045	1,038		Algorithm converged.	0,815	1,322	0,7627		0,963		Algorithm converged.	0,757	1,227
	Geographical region II	USA/Canada	179	9,9	19	10,6	155	8,5	24	15,5	0,65		Algorithm converged.	0,34	1,23	-0,049		Algorithm converged.	-0,121	0,024	0,686		Algorithm converged.	0,391	1,203	0,1880	-	1,459		Algorithm converged.	0,831	2,559
		Western Europe	588	32,5	106	18,0	572	31,4	89	15,6	1,19		Algorithm converged.	0,88	1,63	0,025		Algorithm converged.	-0,018	0,068	1,159		Algorithm converged.	0,896	1,498	0,2619		0,863		Algorithm converged.	0,667	1,116
		Asia Pacific	415	22,9	70	16,9	427	23,4	66	15,5	1,11		Algorithm converged.	0,77	1,60	0,014		Algorithm converged.	-0,036	0,064	1,091		Algorithm converged.	0,802	1,485	0,5783		0,916		Algorithm converged.	0,673	1,247
		Latin America	34	1,9	2	5,9	36	2,0	4	11,1	0,50		Algorithm converged.	0,09	2,93	-0,052		Algorithm converged.	-0,182	0,077	0,529		Algorithm converged.	0,104	2,706	0,4448		1,889		Algorithm converged.	0,370	9,654
		Other	147	8,1	22	15,0	131	7,2	18	13,7	1,10		Algorithm converged.	0,56	2,17	0,012		Algorithm converged.	-0,070	0,095	1,089		Algorithm converged.	0,612	1,939	0,7715		0,918		Algorithm converged.	0,516	1,634
	Protocol version	Protocol A	958	52,9	154	16,1	912	50,0	139	15,2	1,07		Algorithm converged.	0,83	1,37	0,008		Algorithm converged.	-0,025	0,041	1,055		Algorithm converged.	0,854	1,302	0,6201	0,9844	0,948		Algorithm converged.	0,768	1,170
		Protocol amendment B	405	22,4	65	16,0	409	22,4	62	15,2	1,07		Algorithm converged.	0,73	1,56	0,009		Algorithm converged.	-0,041	0,059	1,059		Algorithm converged.	0,769	1,458	0,7263		0,945		Algorithm converged.	0,686	1,300
	Nodal status	0 positive nodes	257	14,2	39	15,2	257	14,1	41	16,0	0,94		Algorithm converged.	0,58	1,52	-0,008		Algorithm converged.	-0,070	0,055	0,951		Algorithm converged.	0,636	1,423	0,8078	0,5720	1,051		Algorithm converged.	0,703	1,573
		>= 1 positive nodes	1106	61,1	180	16,3	1064	58,4	160	15,0	1,10		Algorithm converged.	0,87	1,38	0,012		Algorithm converged.	-0,018	0,043	1,082		Algorithm converged.	0,890	1,316	0,4282		0,924		Algorithm converged.	0,760	1,124
	Menopausal status at randomization	Premenopausal	663	36,6	105	15,8	657	36,0	99	15,1	1,06		Algorithm converged.	0,79	1,43	0,008		Algorithm converged.	-0,031	0,047	1,051		Algorithm converged.	0,816	1,353	0,6994	0,9327	0,951		Algorithm converged.	0,739	1,225
		Postmenopausal	696	38,4	114	16,4	658	36,1	101	15,3	1,08		Algorithm converged.	0,81	1,45	0,010		Algorithm converged.	-0,029	0,049	1,067		Algorithm converged.	0,835	1,364	0,6045		0,937		Algorithm converged.	0,733	1,198

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	6	0,3	1	16,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1210	66,8	188	15,5	1179	64,7	172	14,6	1,08		Algorithm converged.	0,86	1,35	0,009		Algorithm converged.	-0,019	0,038	1,065		Algorithm converged.	0,880	1,289	0,5172	0,7770	0,939		Algorithm converged.	0,776	1,136
		>= 65	153	8,4	31	20,3	142	7,8	29	20,4	0,99		Algorithm converged.	0,56	1,75	-0,002		Algorithm converged.	-0,094	0,090	0,992		Algorithm converged.	0,631	1,559	0,9726		1,008		Algorithm converged.	0,641	1,584
	Histological grade	Grade 1	26	1,4	6	23,1	20	1,1	5	25,0	0,90		Algorithm converged.	0,23	3,52	-0,019		Algorithm converged.	-0,269	0,230	0,923		Algorithm converged.	0,328	2,595	0,8794	0,5326	1,083		Algorithm converged.	0,385	3,046
		Grade 2	428	23,6	72	16,8	407	22,3	55	13,5	1,29		Algorithm converged.	0,88	1,89	0,033		Algorithm converged.	-0,015	0,082	1,245		Algorithm converged.	0,901	1,721	0,1848		0,803		Algorithm converged.	0,581	1,110
		Grade 3	860	47,5	135	15,7	843	46,2	132	15,7	1,00		Algorithm converged.	0,77	1,30	0,000		Algorithm converged.	-0,034	0,035	1,003		Algorithm converged.	0,804	1,250	0,9822		0,997		Algorithm converged.	0,800	1,243
		Unevaluable/Unknown/Missing	49	2,7	6	12,2	51	2,8	9	17,6	0,65		Algorithm converged.	0,21	1,99	-0,054		Algorithm converged.	-0,193	0,085	0,694		Algorithm converged.	0,267	1,804	0,4536		1,441		Algorithm converged.	0,554	3,748
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	93	17,0	515	28,3	85	16,5	1,04		Algorithm converged.	0,75	1,43	0,005		Algorithm converged.	-0,040	0,050	1,030		Algorithm converged.	0,788	1,347	0,8285	0,8223	0,971		Algorithm converged.	0,742	1,270
		Mastectomy	816	45,1	126	15,4	806	44,2	116	14,4	1,09		Algorithm converged.	0,83	1,43	0,010		Algorithm converged.	-0,024	0,045	1,073		Algorithm converged.	0,850	1,354	0,5534		0,932		Algorithm converged.	0,739	1,176
	Tumor size	0 - < 2 cm	516	28,5	81	15,7	489	26,8	74	15,1	1,04		Algorithm converged.	0,74	1,47	0,006		Algorithm converged.	-0,039	0,050	1,037		Algorithm converged.	0,776	1,386	0,8044	0,0132	0,964		Algorithm converged.	0,721	1,288

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	745	41,1	116	15,6	716	39,3	118	16,5	0,93		Algorithm converged.	0,71	1,24	-0,009		Algorithm converged.	-0,047	0,029	0,945		Algorithm converged.	0,747	1,195	0,6355		1,058		Algorithm converged.	0,837	1,339
		>= 5 cm	100	5,5	22	22,0	114	6,3	9	7,9	3,29		Algorithm converged.	1,44	7,54	0,141		Algorithm converged.	0,046	0,236	2,787		Algorithm converged.	1,346	5,768	0,0058		0,359		Algorithm converged.	0,173	0,743
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1042	57,5	159	15,3	1006	55,2	156	15,5	0,98		Algorithm converged.	0,77	1,25	-0,002		Algorithm converged.	-0,034	0,029	0,984		Algorithm converged.	0,803	1,206	0,8765	0,1694	1,016		Algorithm converged.	0,829	1,245
		No	321	17,7	60	18,7	315	17,3	45	14,3	1,38		Algorithm converged.	0,90	2,10	0,044		Algorithm converged.	-0,013	0,102	1,308		Algorithm converged.	0,918	1,864	0,1365		0,764		Algorithm converged.	0,537	1,089
	Race	White	896	49,5	143	16,0	874	47,9	131	15,0	1,08		Algorithm converged.	0,83	1,39	0,010		Algorithm converged.	-0,024	0,043	1,065		Algorithm converged.	0,856	1,324	0,5723	-	0,939		Algorithm converged.	0,755	1,168
		Black	18	1,0	3	16,7	19	1,0	2	10,5	1,70		Algorithm converged.	0,25	11,59	0,061		Algorithm converged.	-0,159	0,282	1,583		Algorithm converged.	0,298	8,403	0,5894		0,632		Algorithm converged.	0,119	3,352
		Asian	400	22,1	69	17,3	394	21,6	64	16,2	1,07		Algorithm converged.	0,74	1,56	0,010		Algorithm converged.	-0,042	0,062	1,062		Algorithm converged.	0,779	1,448	0,7043		0,942		Algorithm converged.	0,690	1,284
		Other	44	2,4	4	9,1	33	1,8	4	12,1	0,73		Algorithm converged.	0,17	3,14	-0,030		Algorithm converged.	-0,170	0,110	0,750		Algorithm converged.	0,202	2,781	0,6670		1,333		Algorithm converged.	0,360	4,943
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC07_W15_SG.xls
26OCT2020 16:19

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Diarrhea Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	458	29,9	1590	87,2	213	13,4	2,76		Algorithm converged.	2,30	3,30	0,165		Algorithm converged.	0,137	0,193		2,232		Algorithm converged.	1,927	2,584	<.0001		0,448		Algorithm converged.	0,387	0,519
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	14	32,6	35	1,9	3	8,6	5,15		Algorithm converged.	1,34	19,75	0,240		Algorithm converged.	0,072	0,408		3,798		Algorithm converged.	1,186	12,170	0,0247	0,1630	0,263		Algorithm converged.	0,082	0,843
		0 positive nodes, tumor > 1 cm	225	12,4	63	28,0	248	13,6	43	17,3	1,85		Algorithm converged.	1,20	2,88	0,107		Algorithm converged.	0,031	0,182		1,615		Algorithm converged.	1,146	2,276	0,0062		0,619		Algorithm converged.	0,439	0,873
		1-3 positive nodes	766	42,3	226	29,5	790	43,3	94	11,9	3,10		Algorithm converged.	2,38	4,04	0,176		Algorithm converged.	0,137	0,215		2,480		Algorithm converged.	1,992	3,087	<.0001		0,403		Algorithm converged.	0,324	0,502
		>= 4 positive nodes	498	27,5	155	31,1	517	28,4	73	14,1	2,75		Algorithm converged.	2,01	3,75	0,170		Algorithm converged.	0,120	0,221		2,204		Algorithm converged.	1,718	2,829	<.0001		0,454		Algorithm converged.	0,353	0,582
	Adjuvant chemotherapy regimen	Anthracycline	1226	67,7	362	29,5	1273	69,8	173	13,6	2,66		Algorithm converged.	2,18	3,26	0,159		Algorithm converged.	0,128	0,191		2,173		Algorithm converged.	1,845	2,558	<.0001	0,4733	0,460		Algorithm converged.	0,391	0,542
		Non-anthracycline	306	16,9	96	31,4	317	17,4	40	12,6	3,17		Algorithm converged.	2,10	4,77	0,188		Algorithm converged.	0,124	0,251		2,486		Algorithm converged.	1,781	3,471	<.0001		0,402		Algorithm converged.	0,288	0,562
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	745	41,1	229	30,7	750	41,1	110	14,7	2,58		Algorithm converged.	2,00	3,33	0,161		Algorithm converged.	0,119	0,202		2,096		Algorithm converged.	1,710	2,569	<.0001	0,4063	0,477		Algorithm converged.	0,389	0,585
		Positive (ER and/or PgR positive)	787	43,5	229	29,1	840	46,1	103	12,3	2,94		Algorithm converged.	2,27	3,80	0,168		Algorithm converged.	0,130	0,207		2,373		Algorithm converged.	1,921	2,931	<.0001		0,421		Algorithm converged.	0,341	0,521

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	76	35,7	224	12,3	34	15,2	3,10		Algorithm converged.	1,96	4,91	0,205		Algorithm converged.	0,125	0,285	2,351		Algorithm converged.	1,643	3,363	<.0001	0,5931	0,425		Algorithm converged.	0,297	0,609
		Western Europe	658	36,3	231	35,1	674	37,0	96	14,2	3,26		Algorithm converged.	2,49	4,26	0,209		Algorithm converged.	0,164	0,254	2,465		Algorithm converged.	1,993	3,048	<.0001		0,406		Algorithm converged.	0,328	0,502
		Asia Pacific	461	25,5	109	23,6	487	26,7	58	11,9	2,29		Algorithm converged.	1,62	3,24	0,117		Algorithm converged.	0,069	0,166	1,985		Algorithm converged.	1,483	2,658	<.0001		0,504		Algorithm converged.	0,376	0,674
		Latin America	38	2,1	6	15,8	42	2,3	4	9,5	1,78		Algorithm converged.	0,46	6,87	0,063		Algorithm converged.	-0,083	0,209	1,658		Algorithm converged.	0,506	5,431	0,4037		0,603		Algorithm converged.	0,184	1,976
		Other	162	8,9	36	22,2	163	8,9	21	12,9	1,93		Algorithm converged.	1,07	3,48	0,093		Algorithm converged.	0,011	0,176	1,725		Algorithm converged.	1,054	2,822	0,0300		0,580		Algorithm converged.	0,354	0,949
	Protocol version	Protocol A	1048	57,9	317	30,2	1088	59,7	153	14,1	2,65		Algorithm converged.	2,14	3,29	0,162		Algorithm converged.	0,127	0,196	2,151		Algorithm converged.	1,809	2,558	<.0001	0,4488	0,465		Algorithm converged.	0,391	0,553
		Protocol amendment B	484	26,7	141	29,1	502	27,5	60	12,0	3,03		Algorithm converged.	2,17	4,23	0,172		Algorithm converged.	0,122	0,221	2,437		Algorithm converged.	1,851	3,209	<.0001		0,410		Algorithm converged.	0,312	0,540
	Nodal status	0 positive nodes	268	14,8	77	28,7	283	15,5	46	16,3	2,08		Algorithm converged.	1,38	3,14	0,125		Algorithm converged.	0,056	0,194	1,768		Algorithm converged.	1,277	2,446	0,0006	0,1251	0,566		Algorithm converged.	0,409	0,783
		>= 1 positive nodes	1264	69,8	381	30,1	1307	71,7	167	12,8	2,95		Algorithm converged.	2,41	3,60	0,174		Algorithm converged.	0,143	0,205	2,359		Algorithm converged.	2,001	2,781	<.0001		0,424		Algorithm converged.	0,360	0,500
	Menopausal status at randomization	Premenopausal	750	41,4	222	29,6	796	43,7	98	12,3	2,99		Algorithm converged.	2,30	3,90	0,173		Algorithm converged.	0,133	0,213	2,404		Algorithm converged.	1,938	2,983	<.0001	0,3853	0,416		Algorithm converged.	0,335	0,516
		Postmenopausal	778	43,0	236	30,3	786	43,1	113	14,4	2,59		Algorithm converged.	2,02	3,33	0,160		Algorithm converged.	0,119	0,200	2,110		Algorithm converged.	1,726	2,580	<.0001		0,474		Algorithm converged.	0,388	0,580

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	8	0,4	2	25,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1354	74,8	410	30,3	1415	77,6	188	13,3	2,83		Algorithm converged.	2,34	3,44	0,170		Algorithm converged.	0,140	0,200	2,279		Algorithm converged.	1,950	2,663	<.0001	0,4307	0,439		Algorithm converged.	0,375	0,513
		>= 65	178	9,8	48	27,0	175	9,6	25	14,3	2,22		Algorithm converged.	1,29	3,79	0,127		Algorithm converged.	0,044	0,210	1,888		Algorithm converged.	1,220	2,919	0,0043		0,530		Algorithm converged.	0,343	0,819
	Histological grade	Grade 1	27	1,5	5	18,5	22	1,2	5	22,7	0,77		Algorithm converged.	0,19	3,11	-0,042		Algorithm converged.	-0,270	0,186	0,815		Algorithm converged.	0,270	2,459	0,7163	0,1363	1,227		Algorithm converged.	0,407	3,703
		Grade 2	472	26,1	135	28,6	485	26,6	54	11,1	3,20		Algorithm converged.	2,26	4,52	0,175		Algorithm converged.	0,125	0,224	2,569		Algorithm converged.	1,924	3,430	<.0001		0,389		Algorithm converged.	0,292	0,520
		Grade 3	974	53,8	302	31,0	1024	56,2	146	14,3	2,70		Algorithm converged.	2,17	3,37	0,167		Algorithm converged.	0,131	0,204	2,175		Algorithm converged.	1,822	2,596	<.0001		0,460		Algorithm converged.	0,385	0,549
		Unevaluable/Unknown/Missing	59	3,3	16	27,1	59	3,2	8	13,6	2,37		Algorithm converged.	0,93	6,08	0,136		Algorithm converged.	-0,008	0,279	2,000		Algorithm converged.	0,928	4,312	0,0770		0,500		Algorithm converged.	0,232	1,078
	Type of surgery for primary tumor	Breast conserving surgery	604	33,4	196	32,5	599	32,9	77	12,9	3,26		Algorithm converged.	2,43	4,37	0,196		Algorithm converged.	0,150	0,242	2,524		Algorithm converged.	1,989	3,203	<.0001	0,1805	0,396		Algorithm converged.	0,312	0,503
		Mastectomy	928	51,2	262	28,2	990	54,3	136	13,7	2,47		Algorithm converged.	1,96	3,11	0,145		Algorithm converged.	0,109	0,181	2,055		Algorithm converged.	1,705	2,477	<.0001		0,487		Algorithm converged.	0,404	0,587
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	564	31,1	173	30,7	579	31,8	75	13,0	2,97		Algorithm converged.	2,20	4,02	0,177		Algorithm converged.	0,130	0,224	2,368		Algorithm converged.	1,854	3,025	<.0001	0,5865	0,422		Algorithm converged.	0,331	0,539

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	843	46,5	245	29,1	860	47,2	111	12,9	2,76		Algorithm converged.	2,16	3,55	0,162		Algorithm converged.	0,124	0,200	2,252		Algorithm converged.	1,838	2,759	<.0001		0,444		Algorithm converged.	0,362	0,544
		>= 5 cm	123	6,8	39	31,7	149	8,2	26	17,4	2,20		Algorithm converged.	1,24	3,88	0,143		Algorithm converged.	0,040	0,245	1,817		Algorithm converged.	1,176	2,807	0,0071		0,550		Algorithm converged.	0,356	0,850
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1184	65,4	370	31,3	1201	65,9	163	13,6	2,89		Algorithm converged.	2,36	3,56	0,177		Algorithm converged.	0,144	0,210	2,303		Algorithm converged.	1,951	2,718	<.0001	0,3900	0,434		Algorithm converged.	0,368	0,513
		No	348	19,2	88	25,3	389	21,3	50	12,9	2,29		Algorithm converged.	1,56	3,37	0,124		Algorithm converged.	0,068	0,181	1,967		Algorithm converged.	1,435	2,697	<.0001		0,508		Algorithm converged.	0,371	0,697
	Race	White	1011	55,8	340	33,6	1056	57,9	152	14,4	3,01		Algorithm converged.	2,43	3,74	0,192		Algorithm converged.	0,156	0,228	2,336		Algorithm converged.	1,970	2,771	<.0001	-	0,428		Algorithm converged.	0,361	0,508
		Black	21	1,2	3	14,3	27	1,5	4	14,8	0,96		Algorithm converged.	0,19	4,84	-0,005		Algorithm converged.	-0,206	0,196	0,964		Algorithm converged.	0,242	3,849	0,9589		1,037		Algorithm converged.	0,260	4,139
		Asian	449	24,8	105	23,4	459	25,2	50	10,9	2,50		Algorithm converged.	1,73	3,60	0,125		Algorithm converged.	0,076	0,173	2,147		Algorithm converged.	1,574	2,929	<.0001		0,466		Algorithm converged.	0,341	0,636
		Other	47	2,6	9	19,1	47	2,6	7	14,9	1,35		Algorithm converged.	0,46	4,00	0,043		Algorithm converged.	-0,109	0,194	1,286		Algorithm converged.	0,522	3,166	0,5847		0,778		Algorithm converged.	0,316	1,915
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1358	75,0	100	7,4	1322	72,5	128	9,7	0,74		Algorithm converged.	0,56	0,97	-0,023		Algorithm converged.	-0,044	-0,002	0,761		Algorithm converged.	0,592	0,977	0,0321		1,315		Algorithm converged.	1,024	1,689

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	5	11,4	35	1,9	2	5,7	2,12		Algorithm converged.	0,38	11,63	0,056		Algorithm converged.	-0,065	0,178	1,989		Algorithm converged.	0,410	9,641	0,3934	-	0,503		Algorithm converged.	0,104	2,438
		0 positive nodes, tumor > 1 cm	213	11,8	11	5,2	222	12,2	21	9,5	0,52		Algorithm converged.	0,24	1,11	-0,043		Algorithm converged.	-0,092	0,006	0,546		Algorithm converged.	0,270	1,105	0,0924		1,832		Algorithm converged.	0,905	3,707
		1-3 positive nodes	691	38,2	59	8,5	653	35,8	60	9,2	0,92		Algorithm converged.	0,63	1,34	-0,007		Algorithm converged.	-0,037	0,024	0,929		Algorithm converged.	0,659	1,310	0,6751		1,076		Algorithm converged.	0,764	1,517
		>= 4 positive nodes	410	22,6	25	6,1	412	22,6	45	10,9	0,53		Algorithm converged.	0,32	0,88	-0,048		Algorithm converged.	-0,086	-0,010	0,558		Algorithm converged.	0,349	0,893	0,0149		1,791		Algorithm converged.	1,120	2,864
	Adjuvant chemotherapy regimen	Anthracycline	1083	59,8	82	7,6	1061	58,2	101	9,5	0,78		Algorithm converged.	0,57	1,06	-0,019		Algorithm converged.	-0,043	0,004	0,795		Algorithm converged.	0,602	1,051	0,1075	0,4787	1,257		Algorithm converged.	0,951	1,661
		Non-anthracycline	275	15,2	18	6,5	261	14,3	27	10,3	0,61		Algorithm converged.	0,33	1,13	-0,038		Algorithm converged.	-0,085	0,009	0,633		Algorithm converged.	0,357	1,121	0,1167		1,580		Algorithm converged.	0,892	2,800
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	661	36,5	43	6,5	643	35,3	65	10,1	0,62		Algorithm converged.	0,41	0,92	-0,036		Algorithm converged.	-0,066	-0,006	0,644		Algorithm converged.	0,445	0,931	0,0194	0,2200	1,554		Algorithm converged.	1,074	2,249
		Positive (ER and/or PgR positive)	697	38,5	57	8,2	679	37,2	63	9,3	0,87		Algorithm converged.	0,60	1,27	-0,011		Algorithm converged.	-0,041	0,019	0,881		Algorithm converged.	0,626	1,241	0,4698		1,135		Algorithm converged.	0,806	1,598
	Geographical region II	USA/Canada	178	9,8	13	7,3	155	8,5	13	8,4	0,86		Algorithm converged.	0,39	1,92	-0,011		Algorithm converged.	-0,069	0,047	0,871		Algorithm converged.	0,416	1,821	0,7133	-	1,148		Algorithm converged.	0,549	2,402
		Western Europe	585	32,3	50	8,5	572	31,4	59	10,3	0,81		Algorithm converged.	0,55	1,21	-0,018		Algorithm converged.	-0,051	0,016	0,829		Algorithm converged.	0,579	1,186	0,3043		1,207		Algorithm converged.	0,843	1,727
		Asia Pacific	414	22,9	30	7,2	428	23,5	36	8,4	0,85		Algorithm converged.	0,51	1,41	-0,012		Algorithm converged.	-0,048	0,025	0,862		Algorithm converged.	0,541	1,372	0,5301		1,161		Algorithm converged.	0,729	1,848

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	34	1,9	0	0,0	36	2,0	3	8,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	0,9999		>999		Algorithm converged.	0,000	NE
		Other	147	8,1	7	4,8	131	7,2	17	13,0	0,34		Algorithm converged.	0,13	0,84	-0,082		Algorithm converged.	-0,149	-0,015	0,367		Algorithm converged.	0,157	0,857	0,0205		2,725		Algorithm converged.	1,167	6,364
	Protocol version	Protocol A	955	52,7	67	7,0	914	50,1	92	10,1	0,67		Algorithm converged.	0,49	0,94	-0,030		Algorithm converged.	-0,056	-0,005	0,697		Algorithm converged.	0,516	0,942	0,0189	0,3021	1,435		Algorithm converged.	1,061	1,939
		Protocol amendment B	403	22,3	33	8,2	408	22,4	36	8,8	0,92		Algorithm converged.	0,56	1,51	-0,006		Algorithm converged.	-0,045	0,032	0,928		Algorithm converged.	0,591	1,458	0,7460		1,078		Algorithm converged.	0,686	1,693
	Nodal status	0 positive nodes	257	14,2	16	6,2	257	14,1	23	8,9	0,68		Algorithm converged.	0,35	1,31	-0,027		Algorithm converged.	-0,073	0,018	0,696		Algorithm converged.	0,376	1,286	0,2468	0,7557	1,437		Algorithm converged.	0,778	2,657
		>= 1 positive nodes	1101	60,8	84	7,6	1065	58,4	105	9,9	0,76		Algorithm converged.	0,56	1,02	-0,022		Algorithm converged.	-0,046	0,002	0,774		Algorithm converged.	0,588	1,018	0,0669		1,292		Algorithm converged.	0,982	1,700
	Menopausal status at randomization	Premenopausal	661	36,5	42	6,4	658	36,1	50	7,6	0,83		Algorithm converged.	0,54	1,26	-0,012		Algorithm converged.	-0,040	0,015	0,836		Algorithm converged.	0,563	1,242	0,3756	0,6193	1,196		Algorithm converged.	0,805	1,777
		Postmenopausal	693	38,3	58	8,4	658	36,1	75	11,4	0,71		Algorithm converged.	0,50	1,02	-0,030		Algorithm converged.	-0,062	0,002	0,734		Algorithm converged.	0,530	1,017	0,0631		1,362		Algorithm converged.	0,983	1,886

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	6	0,3	3	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Age II	< 65	1206	66,6	87	7,2	1180	64,7	114	9,7	0,73		Algorithm converged.	0,54	0,97	-0,024		Algorithm converged.	-0,047	-0,002	0,747		Algorithm converged.	0,572	0,975	0,0322	0,7022	1,339		Algorithm converged.	1,025	1,749
		>= 65	152	8,4	13	8,6	142	7,8	14	9,9	0,86		Algorithm converged.	0,39	1,89	-0,013		Algorithm converged.	-0,079	0,053	0,867		Algorithm converged.	0,422	1,781	0,6985		1,153		Algorithm converged.	0,561	2,367
	Histological grade	Grade 1	26	1,4	2	7,7	20	1,1	3	15,0	0,47		Algorithm converged.	0,07	3,14	-0,073		Algorithm converged.	-0,260	0,114	0,513		Algorithm converged.	0,094	2,784	0,4391	-	1,950		Algorithm converged.	0,359	10,585
		Grade 2	426	23,5	32	7,5	406	22,3	34	8,4	0,89		Algorithm converged.	0,54	1,47	-0,009		Algorithm converged.	-0,045	0,028	0,897		Algorithm converged.	0,564	1,425	0,6455		1,115		Algorithm converged.	0,702	1,772
		Grade 3	857	47,3	63	7,4	846	46,4	85	10,0	0,71		Algorithm converged.	0,51	1,00	-0,027		Algorithm converged.	-0,054	0,000	0,732		Algorithm converged.	0,536	0,999	0,0494		1,367		Algorithm converged.	1,001	1,867
		Unevaluable/Unknown/Missing	49	2,7	3	6,1	50	2,7	6	12,0	0,48		Algorithm converged.	0,11	2,03	-0,059		Algorithm converged.	-0,171	0,054	0,510		Algorithm converged.	0,135	1,927	0,3209		1,960		Algorithm converged.	0,519	7,401
	Type of surgery for primary tumor	Breast conserving surgery	545	30,1	46	8,4	516	28,3	53	10,3	0,81		Algorithm converged.	0,53	1,22	-0,018		Algorithm converged.	-0,053	0,017	0,822		Algorithm converged.	0,564	1,197	0,3063	0,5842	1,217		Algorithm converged.	0,835	1,773
		Mastectomy	813	44,9	54	6,6	806	44,2	75	9,3	0,69		Algorithm converged.	0,48	1,00	-0,027		Algorithm converged.	-0,053	0,000	0,714		Algorithm converged.	0,510	0,999	0,0492		1,401		Algorithm converged.	1,001	1,960
	Tumor size	0 - < 2 cm	515	28,4	47	9,1	489	26,8	42	8,6	1,07		Algorithm converged.	0,69	1,65	0,005		Algorithm converged.	-0,030	0,041	1,063		Algorithm converged.	0,714	1,581	0,7647	0,0973	0,941		Algorithm converged.	0,633	1,400

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	741	40,9	46	6,2	718	39,4	75	10,4	0,57		Algorithm converged.	0,39	0,83	-0,042		Algorithm converged.	-0,071	-0,014	0,594		Algorithm converged.	0,418	0,845	0,0038		1,683		Algorithm converged.	1,183	2,394
		>= 5 cm	100	5,5	7	7,0	113	6,2	11	9,7	0,70		Algorithm converged.	0,26	1,88	-0,027		Algorithm converged.	-0,101	0,047	0,719		Algorithm converged.	0,290	1,784	0,4769		1,391		Algorithm converged.	0,561	3,450
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1038	57,3	81	7,8	1007	55,2	95	9,4	0,81		Algorithm converged.	0,60	1,11	-0,016		Algorithm converged.	-0,041	0,008	0,827		Algorithm converged.	0,623	1,098	0,1895	0,2214	1,209		Algorithm converged.	0,911	1,605
		No	320	17,7	19	5,9	315	17,3	33	10,5	0,54		Algorithm converged.	0,30	0,97	-0,045		Algorithm converged.	-0,088	-0,003	0,567		Algorithm converged.	0,329	0,975	0,0403		1,764		Algorithm converged.	1,026	3,036
	Race	White	893	49,3	68	7,6	874	47,9	91	10,4	0,71		Algorithm converged.	0,51	0,99	-0,028		Algorithm converged.	-0,055	-0,001	0,731		Algorithm converged.	0,542	0,987	0,0410	-	1,367		Algorithm converged.	1,013	1,846
		Black	18	1,0	0	0,0	19	1,0	1	5,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
		Asian	398	22,0	30	7,5	395	21,7	33	8,4	0,89		Algorithm converged.	0,53	1,50	-0,008		Algorithm converged.	-0,046	0,029	0,902		Algorithm converged.	0,561	1,450	0,6708		1,108		Algorithm converged.	0,690	1,781
		Other	44	2,4	2	4,5	33	1,8	3	9,1	0,48		Algorithm converged.	0,07	3,03	-0,045		Algorithm converged.	-0,161	0,070	0,500		Algorithm converged.	0,089	2,824	0,4326		2,000		Algorithm converged.	0,354	11,296
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC08_W15_SG.xls
26OCT2020 16:22

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Financial Difficulties Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO												PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1524	84,2	255	16,7	1586	87,0	276	17,4	0,95		Algorithm converged.	0,79	1,15	-0,007		Algorithm converged.	-0,033	0,020		0,962		Algorithm converged.	0,823	1,123	0,6197			1,040		Algorithm converged.	0,891	1,214
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	11	25,6	35	1,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	0,0004		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	221	12,2	33	14,9	248	13,6	53	21,4	0,65		Algorithm converged.	0,40	1,04	-0,064		Algorithm converged.	-0,134	0,005		0,699		Algorithm converged.	0,471	1,037	0,0752			1,431		Algorithm converged.	0,964	2,124
		1-3 positive nodes	763	42,1	129	16,9	786	43,1	129	16,4	1,04		Algorithm converged.	0,79	1,35	0,005		Algorithm converged.	-0,032	0,042		1,030		Algorithm converged.	0,824	1,287	0,7939			0,971		Algorithm converged.	0,777	1,213
		>= 4 positive nodes	497	27,4	82	16,5	517	28,4	94	18,2	0,89		Algorithm converged.	0,64	1,23	-0,017		Algorithm converged.	-0,063	0,030		0,907		Algorithm converged.	0,693	1,188	0,4798			1,102		Algorithm converged.	0,842	1,443
	Adjuvant chemotherapy regimen	Anthracycline	1221	67,4	202	16,5	1269	69,6	210	16,5	1,00		Algorithm converged.	0,81	1,24	0,000		Algorithm converged.	-0,029	0,029		1,000		Algorithm converged.	0,838	1,193	0,9975	0,3560		1,000		Algorithm converged.	0,838	1,193
		Non-anthracycline	303	16,7	53	17,5	317	17,4	66	20,8	0,81		Algorithm converged.	0,54	1,20	-0,033		Algorithm converged.	-0,095	0,029		0,840		Algorithm converged.	0,607	1,163	0,2941			1,190		Algorithm converged.	0,860	1,648
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	741	40,9	118	15,9	750	41,1	125	16,7	0,95		Algorithm converged.	0,72	1,25	-0,007		Algorithm converged.	-0,045	0,030		0,955		Algorithm converged.	0,759	1,203	0,6981	0,9310		1,047		Algorithm converged.	0,831	1,317
		Positive (ER and/or PgR positive)	783	43,2	137	17,5	836	45,9	151	18,1	0,96		Algorithm converged.	0,75	1,24	-0,006		Algorithm converged.	-0,043	0,032		0,969		Algorithm converged.	0,785	1,195	0,7663			1,032		Algorithm converged.	0,837	1,273

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	212	11,7	36	17,0	224	12,3	40	17,9	0,94		Algorithm converged.	0,57	1,54	-0,009		Algorithm converged.	-0,080	0,062	0,951		Algorithm converged.	0,632	1,432	0,8096	0,9239	1,052		Algorithm converged.	0,698	1,583
		Western Europe	652	36,0	121	18,6	671	36,8	128	19,1	0,97		Algorithm converged.	0,73	1,27	-0,005		Algorithm converged.	-0,047	0,037	0,973		Algorithm converged.	0,778	1,217	0,8097		1,028		Algorithm converged.	0,822	1,286
		Asia Pacific	460	25,4	61	13,3	486	26,7	70	14,4	0,91		Algorithm converged.	0,63	1,32	-0,011		Algorithm converged.	-0,055	0,033	0,921		Algorithm converged.	0,669	1,266	0,6113		1,086		Algorithm converged.	0,790	1,494
		Latin America	38	2,1	8	21,1	42	2,3	6	14,3	1,60		Algorithm converged.	0,50	5,12	0,068		Algorithm converged.	-0,100	0,235	1,474		Algorithm converged.	0,562	3,861	0,4301		0,679		Algorithm converged.	0,259	1,778
		Other	162	8,9	29	17,9	163	8,9	32	19,6	0,89		Algorithm converged.	0,51	1,56	-0,017		Algorithm converged.	-0,102	0,068	0,912		Algorithm converged.	0,580	1,434	0,6897		1,097		Algorithm converged.	0,697	1,725
	Protocol version	Protocol A	1043	57,6	160	15,3	1083	59,4	185	17,1	0,88		Algorithm converged.	0,70	1,11	-0,017		Algorithm converged.	-0,049	0,014	0,898		Algorithm converged.	0,740	1,090	0,2766	0,2364	1,114		Algorithm converged.	0,917	1,352
		Protocol amendment B	481	26,6	95	19,8	503	27,6	91	18,1	1,11		Algorithm converged.	0,81	1,53	0,017		Algorithm converged.	-0,032	0,066	1,092		Algorithm converged.	0,843	1,414	0,5065		0,916		Algorithm converged.	0,707	1,187
	Nodal status	0 positive nodes	264	14,6	44	16,7	283	15,5	53	18,7	0,87		Algorithm converged.	0,56	1,35	-0,021		Algorithm converged.	-0,085	0,043	0,890		Algorithm converged.	0,619	1,279	0,5288	0,6428	1,124		Algorithm converged.	0,782	1,615
		>= 1 positive nodes	1260	69,6	211	16,7	1303	71,5	223	17,1	0,97		Algorithm converged.	0,79	1,20	-0,004		Algorithm converged.	-0,033	0,025	0,978		Algorithm converged.	0,824	1,162	0,8037		1,022		Algorithm converged.	0,861	1,213
	Menopausal status at randomization	Premenopausal	748	41,3	127	17,0	792	43,4	144	18,2	0,92		Algorithm converged.	0,71	1,20	-0,012		Algorithm converged.	-0,050	0,026	0,934		Algorithm converged.	0,752	1,160	0,5357	0,6911	1,071		Algorithm converged.	0,862	1,330
		Postmenopausal	772	42,6	127	16,5	786	43,1	130	16,5	0,99		Algorithm converged.	0,76	1,30	-0,001		Algorithm converged.	-0,038	0,036	0,995		Algorithm converged.	0,795	1,244	0,9624		1,005		Algorithm converged.	0,804	1,257
		Unknown/Missing	4	0,2	1	25,0	8	0,4	2	25,0	1,00		Algorithm converged.	0,06	15,99	0,000		Algorithm converged.	-0,520	0,520	1,000		Algorithm converged.	0,125	7,995	1,0000		1,000		Algorithm converged.	0,125	7,995
	Age II	< 65	1347	74,4	230	17,1	1413	77,5	248	17,6	0,97		Algorithm converged.	0,79	1,18	-0,005		Algorithm converged.	-0,033	0,023	0,973		Algorithm converged.	0,826	1,145	0,7410	0,6836	1,028		Algorithm converged.	0,873	1,210
		>= 65	177	9,8	25	14,1	173	9,5	28	16,2	0,85		Algorithm converged.	0,47	1,53	-0,021		Algorithm converged.	-0,096	0,055	0,873		Algorithm converged.	0,531	1,434	0,5912		1,146		Algorithm converged.	0,697	1,883

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	6	22,2	22	1,2	2	9,1	2,86		Algorithm converged.	0,51	15,85	0,131		Algorithm converged.	-0,066	0,329	2,444		Algorithm converged.	0,547	10,934	0,2422	-	0,409		Algorithm converged.	0,091	1,830
		Grade 2	470	26,0	80	17,0	485	26,6	80	16,5	1,04		Algorithm converged.	0,74	1,46	0,005		Algorithm converged.	-0,042	0,053	1,032		Algorithm converged.	0,778	1,369	0,8276		0,969		Algorithm converged.	0,730	1,286
		Grade 3	969	53,5	165	17,0	1020	56,0	183	17,9	0,94		Algorithm converged.	0,74	1,18	-0,009		Algorithm converged.	-0,043	0,024	0,949		Algorithm converged.	0,784	1,149	0,5922		1,054		Algorithm converged.	0,870	1,276
		Unevaluable/Unknown/Missing	58	3,2	4	6,9	59	3,2	11	18,6	0,32		Algorithm converged.	0,10	1,08	-0,117		Algorithm converged.	-0,236	0,001	0,370		Algorithm converged.	0,125	1,095	0,0725		2,703		Algorithm converged.	0,913	8,004
	Type of surgery for primary tumor	Breast conserving surgery	602	33,2	103	17,1	598	32,8	104	17,4	0,98		Algorithm converged.	0,73	1,32	-0,003		Algorithm converged.	-0,046	0,040	0,984		Algorithm converged.	0,768	1,261	0,8973	0,8091	1,016		Algorithm converged.	0,793	1,302
		Mastectomy	922	50,9	152	16,5	987	54,1	172	17,4	0,94		Algorithm converged.	0,74	1,19	-0,009		Algorithm converged.	-0,043	0,024	0,946		Algorithm converged.	0,775	1,154	0,5845		1,057		Algorithm converged.	0,866	1,290
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	559	30,9	97	17,4	579	31,8	92	15,9	1,11		Algorithm converged.	0,81	1,52	0,015		Algorithm converged.	-0,029	0,058	1,092		Algorithm converged.	0,842	1,417	0,5075	0,0365	0,916		Algorithm converged.	0,706	1,188
		>= 2 - < 5 cm	841	46,4	127	15,1	857	47,0	158	18,4	0,79		Algorithm converged.	0,61	1,02	-0,033		Algorithm converged.	-0,069	0,002	0,819		Algorithm converged.	0,662	1,014	0,0667		1,221		Algorithm converged.	0,986	1,511
		>= 5 cm	122	6,7	31	25,4	148	8,1	25	16,9	1,68		Algorithm converged.	0,93	3,03	0,085		Algorithm converged.	-0,013	0,183	1,504		Algorithm converged.	0,941	2,405	0,0881		0,665		Algorithm converged.	0,416	1,063
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1178	65,0	199	16,9	1199	65,8	204	17,0	0,99		Algorithm converged.	0,80	1,23	-0,001		Algorithm converged.	-0,031	0,029	0,993		Algorithm converged.	0,831	1,186	0,9373	0,4759	1,007		Algorithm converged.	0,843	1,203
		No	346	19,1	56	16,2	387	21,2	72	18,6	0,84		Algorithm converged.	0,58	1,24	-0,024		Algorithm converged.	-0,079	0,031	0,870		Algorithm converged.	0,633	1,195	0,3900		1,150		Algorithm converged.	0,837	1,579
	Race	White	1004	55,4	188	18,7	1053	57,8	193	18,3	1,03		Algorithm converged.	0,82	1,28	0,004		Algorithm converged.	-0,030	0,038	1,022		Algorithm converged.	0,852	1,225	0,8170	0,0660	0,979		Algorithm converged.	0,817	1,173
		Black	21	1,2	1	4,8	27	1,5	9	33,3	0,10		Algorithm converged.	0,01	0,87	-0,286		Algorithm converged.	-0,485	-0,086	0,143		Algorithm converged.	0,020	1,041	0,0548		7,000		Algorithm converged.	0,961	50,990
		Asian	448	24,7	58	12,9	458	25,1	67	14,6	0,87		Algorithm converged.	0,59	1,27	-0,017		Algorithm converged.	-0,062	0,028	0,885		Algorithm converged.	0,638	1,227	0,4633		1,130		Algorithm converged.	0,815	1,566
		Other	47	2,6	8	17,0	47	2,6	7	14,9	1,17		Algorithm converged.	0,39	3,54	0,021		Algorithm converged.	-0,127	0,169	1,143		Algorithm converged.	0,451	2,898	0,7785		0,875		Algorithm converged.	0,345	2,218
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1351	74,6	151	11,2	1321	72,5	146	11,1	1,01		Algorithm converged.	0,80	1,29	0,001		Algorithm converged.	-0,023	0,025	1,011		Algorithm converged.	0,816	1,253	0,9184		0,989		Algorithm converged.	0,798	1,225
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	6	13,6	35	1,9	2	5,7	2,61		Algorithm converged.	0,49	13,80	0,079		Algorithm converged.	-0,048	0,206	2,386		Algorithm converged.	0,513	11,104	0,2675	-	0,419		Algorithm converged.	0,090	1,950
		0 positive nodes, tumor > 1 cm	208	11,5	18	8,7	222	12,2	33	14,9	0,54		Algorithm converged.	0,30	1,00	-0,062		Algorithm converged.	-0,123	-0,002	0,582		Algorithm converged.	0,338	1,001	0,0505		1,718		Algorithm converged.	0,999	2,954
		1-3 positive nodes	688	38,0	78	11,3	652	35,8	60	9,2	1,26		Algorithm converged.	0,88	1,80	0,021		Algorithm converged.	-0,011	0,054	1,232		Algorithm converged.	0,895	1,695	0,2000		0,812		Algorithm converged.	0,590	1,117
		>= 4 positive nodes	411	22,7	49	11,9	412	22,6	51	12,4	0,96		Algorithm converged.	0,63	1,46	-0,005		Algorithm converged.	-0,049	0,040	0,963		Algorithm converged.	0,667	1,391	0,8412		1,038		Algorithm converged.	0,719	1,499
	Adjuvant chemotherapy regimen	Anthracycline	1078	59,5	118	10,9	1060	58,1	108	10,2	1,08		Algorithm converged.	0,82	1,43	0,008		Algorithm converged.	-0,018	0,034	1,074		Algorithm converged.	0,839	1,375	0,5691	0,3113	0,931		Algorithm converged.	0,727	1,191

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	273	15,1	33	12,1	261	14,3	38	14,6	0,81		Algorithm converged.	0,49	1,33	-0,025		Algorithm converged.	-0,082	0,033	0,830		Algorithm converged.	0,538	1,282	0,4013		1,204		Algorithm converged.	0,780	1,860
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	658	36,3	64	9,7	643	35,3	82	12,8	0,74		Algorithm converged.	0,52	1,04	-0,030		Algorithm converged.	-0,065	0,004	0,763		Algorithm converged.	0,560	1,038	0,0851	0,0115	1,311		Algorithm converged.	0,963	1,785
		Positive (ER and/or PgR positive)	693	38,3	87	12,6	678	37,2	64	9,4	1,38		Algorithm converged.	0,98	1,94	0,031		Algorithm converged.	-0,002	0,064	1,330		Algorithm converged.	0,980	1,804	0,0668		0,752		Algorithm converged.	0,554	1,020
	Geographical region II	USA/Canada	177	9,8	25	14,1	155	8,5	19	12,3	1,18		Algorithm converged.	0,62	2,23	0,019		Algorithm converged.	-0,054	0,091	1,152		Algorithm converged.	0,661	2,010	0,6175	-	0,868		Algorithm converged.	0,498	1,514
		Western Europe	580	32,0	72	12,4	571	31,3	62	10,9	1,16		Algorithm converged.	0,81	1,67	0,016		Algorithm converged.	-0,021	0,053	1,143		Algorithm converged.	0,831	1,573	0,4112		0,875		Algorithm converged.	0,636	1,204
		Asia Pacific	413	22,8	37	9,0	428	23,5	47	11,0	0,80		Algorithm converged.	0,51	1,26	-0,020		Algorithm converged.	-0,061	0,020	0,816		Algorithm converged.	0,542	1,228	0,3293		1,226		Algorithm converged.	0,814	1,845
		Latin America	34	1,9	3	8,8	36	2,0	5	13,9	0,60		Algorithm converged.	0,13	2,73	-0,051		Algorithm converged.	-0,198	0,097	0,635		Algorithm converged.	0,164	2,457	0,5109		1,574		Algorithm converged.	0,407	6,087
		Other	147	8,1	14	9,5	131	7,2	13	9,9	0,96		Algorithm converged.	0,43	2,11	-0,004		Algorithm converged.	-0,074	0,066	0,960		Algorithm converged.	0,468	1,966	0,9105		1,042		Algorithm converged.	0,509	2,135
	Protocol version	Protocol A	949	52,4	103	10,9	913	50,1	104	11,4	0,95		Algorithm converged.	0,71	1,26	-0,005		Algorithm converged.	-0,034	0,023	0,953		Algorithm converged.	0,737	1,232	0,7123	0,4091	1,050		Algorithm converged.	0,812	1,357
		Protocol amendment B	402	22,2	48	11,9	408	22,4	42	10,3	1,18		Algorithm converged.	0,76	1,83	0,016		Algorithm converged.	-0,027	0,060	1,160		Algorithm converged.	0,785	1,714	0,4566		0,862		Algorithm converged.	0,583	1,274
	Nodal status	0 positive nodes	252	13,9	24	9,5	257	14,1	35	13,6	0,67		Algorithm converged.	0,38	1,16	-0,041		Algorithm converged.	-0,096	0,014	0,699		Algorithm converged.	0,429	1,141	0,1522	0,0954	1,430		Algorithm converged.	0,876	2,333
		>= 1 positive nodes	1099	60,7	127	11,6	1064	58,4	111	10,4	1,12		Algorithm converged.	0,86	1,47	0,011		Algorithm converged.	-0,015	0,038	1,108		Algorithm converged.	0,871	1,409	0,4041		0,903		Algorithm converged.	0,710	1,148
	Menopausal status at randomization	Premenopausal	660	36,4	73	11,1	657	36,0	74	11,3	0,98		Algorithm converged.	0,70	1,38	-0,002		Algorithm converged.	-0,036	0,032	0,982		Algorithm converged.	0,724	1,332	0,9070	0,7528	1,018		Algorithm converged.	0,751	1,381

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	687	37,9	78	11,4	658	36,1	71	10,8	1,06		Algorithm converged.	0,75	1,49	0,006		Algorithm converged.	-0,028	0,039	1,052		Algorithm converged.	0,777	1,425	0,7421		0,950		Algorithm converged.	0,702	1,287
		Unknown/Missing	4	0,2	0	0,0	6	0,3	1	16,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1200	66,3	139	11,6	1180	64,7	131	11,1	1,05		Algorithm converged.	0,81	1,35	0,005		Algorithm converged.	-0,021	0,030	1,043		Algorithm converged.	0,833	1,306	0,7111	0,3855	0,958		Algorithm converged.	0,766	1,200
		>= 65	151	8,3	12	7,9	141	7,7	15	10,6	0,73		Algorithm converged.	0,33	1,61	-0,027		Algorithm converged.	-0,094	0,040	0,747		Algorithm converged.	0,362	1,540	0,4295		1,339		Algorithm converged.	0,649	2,760
	Histological grade	Grade 1	26	1,4	7	26,9	20	1,1	4	20,0	1,47		Algorithm converged.	0,36	5,96	0,069		Algorithm converged.	-0,175	0,314	1,346		Algorithm converged.	0,457	3,969	0,5900	0,8748	0,743		Algorithm converged.	0,252	2,190
		Grade 2	424	23,4	48	11,3	406	22,3	46	11,3	1,00		Algorithm converged.	0,65	1,53	0,000		Algorithm converged.	-0,043	0,043	0,999		Algorithm converged.	0,683	1,462	0,9966		1,001		Algorithm converged.	0,684	1,465
		Grade 3	853	47,1	95	11,1	845	46,4	91	10,8	1,04		Algorithm converged.	0,77	1,41	0,004		Algorithm converged.	-0,026	0,033	1,034		Algorithm converged.	0,788	1,356	0,8082		0,967		Algorithm converged.	0,737	1,268
		Unevaluable/Unknown/Missing	48	2,7	1	2,1	50	2,7	5	10,0	0,19		Algorithm converged.	0,02	1,70	-0,079		Algorithm converged.	-0,172	0,013	0,208		Algorithm converged.	0,025	1,719	0,1451		4,800		Algorithm converged.	0,582	39,599
	Type of surgery for primary tumor	Breast conserving surgery	544	30,0	51	9,4	517	28,4	54	10,4	0,89		Algorithm converged.	0,59	1,33	-0,011		Algorithm converged.	-0,047	0,025	0,898		Algorithm converged.	0,624	1,291	0,5599	0,4135	1,114		Algorithm converged.	0,775	1,602
		Mastectomy	807	44,6	100	12,4	804	44,1	92	11,4	1,09		Algorithm converged.	0,81	1,48	0,009		Algorithm converged.	-0,022	0,041	1,083		Algorithm converged.	0,830	1,413	0,5569		0,923		Algorithm converged.	0,708	1,205

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Tumor size	0 - < 2 cm	509	28,1	48	9,4	489	26,8	49	10,0	0,93		Algorithm converged.	0,61	1,42	-0,006		Algorithm converged.	-0,043	0,031	0,941		Algorithm converged.	0,645	1,374	0,7531	0,7000	1,063		Algorithm converged.	0,728	1,551
		>= 2 - < 5 cm	741	40,9	92	12,4	717	39,3	87	12,1	1,03		Algorithm converged.	0,75	1,40	0,003		Algorithm converged.	-0,031	0,037	1,023		Algorithm converged.	0,778	1,346	0,8698		0,977		Algorithm converged.	0,743	1,286
		>= 5 cm	99	5,5	11	11,1	113	6,2	9	8,0	1,44		Algorithm converged.	0,57	3,64	0,031		Algorithm converged.	-0,048	0,111	1,395		Algorithm converged.	0,603	3,227	0,4365		0,717		Algorithm converged.	0,310	1,658
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1033	57,0	115	11,1	1007	55,2	106	10,5	1,06		Algorithm converged.	0,81	1,41	0,006		Algorithm converged.	-0,021	0,033	1,058		Algorithm converged.	0,824	1,357	0,6596	0,4864	0,946		Algorithm converged.	0,737	1,213
		No	318	17,6	36	11,3	314	17,2	40	12,7	0,87		Algorithm converged.	0,54	1,41	-0,014		Algorithm converged.	-0,065	0,037	0,889		Algorithm converged.	0,582	1,356	0,5840		1,125		Algorithm converged.	0,738	1,717
	Race	White	887	49,0	104	11,7	874	47,9	92	10,5	1,13		Algorithm converged.	0,84	1,52	0,012		Algorithm converged.	-0,017	0,041	1,114		Algorithm converged.	0,855	1,451	0,4243	-	0,898		Algorithm converged.	0,689	1,170
		Black	18	1,0	3	16,7	19	1,0	2	10,5	1,70		Algorithm converged.	0,25	11,59	0,061		Algorithm converged.	-0,159	0,282	1,583		Algorithm converged.	0,298	8,403	0,5894		0,632		Algorithm converged.	0,119	3,352
		Asian	397	21,9	38	9,6	394	21,6	47	11,9	0,78		Algorithm converged.	0,50	1,23	-0,024		Algorithm converged.	-0,067	0,020	0,802		Algorithm converged.	0,536	1,202	0,2858		1,246		Algorithm converged.	0,832	1,867
		Other	44	2,4	6	13,6	33	1,8	5	15,2	0,88		Algorithm converged.	0,25	3,19	-0,015		Algorithm converged.	-0,174	0,144	0,900		Algorithm converged.	0,300	2,697	0,8508		1,111		Algorithm converged.	0,371	3,330
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC09_W15_SG.xls
26OCT2020 16:25

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Global Health Status
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	428	27,9	1589	87,2	421	26,5	1,08		Algorithm converged.	0,92	1,26	0,014		Algorithm converged.	-0,017	0,046		1,054		Algorithm converged.	0,940	1,183	0,3653		0,948		Algorithm converged.	0,846	1,064
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	16	37,2	35	1,9	12	34,3	1,14		Algorithm converged.	0,45	2,89	0,029		Algorithm converged.	-0,184	0,243		1,085		Algorithm converged.	0,595	1,979	0,7896	0,4671	0,921		Algorithm converged.	0,505	1,681
		0 positive nodes, tumor > 1 cm	224	12,4	66	29,5	248	13,6	84	33,9	0,82		Algorithm converged.	0,55	1,20	-0,044		Algorithm converged.	-0,128	0,040		0,870		Algorithm converged.	0,666	1,136	0,3063		1,150		Algorithm converged.	0,880	1,501
		1-3 positive nodes	766	42,3	208	27,2	790	43,3	199	25,2	1,11		Algorithm converged.	0,88	1,39	0,020		Algorithm converged.	-0,024	0,063		1,078		Algorithm converged.	0,912	1,274	0,3783		0,928		Algorithm converged.	0,785	1,096
		>= 4 positive nodes	499	27,6	138	27,7	516	28,3	126	24,4	1,18		Algorithm converged.	0,89	1,57	0,032		Algorithm converged.	-0,022	0,086		1,133		Algorithm converged.	0,920	1,394	0,2404		0,883		Algorithm converged.	0,717	1,087
	Adjuvant chemotherapy regimen	Anthracycline	1226	67,7	347	28,3	1274	69,9	336	26,4	1,10		Algorithm converged.	0,92	1,31	0,019		Algorithm converged.	-0,016	0,054		1,073		Algorithm converged.	0,944	1,220	0,2791	0,5440	0,932		Algorithm converged.	0,820	1,059
		Non-anthracycline	306	16,9	81	26,5	315	17,3	85	27,0	0,97		Algorithm converged.	0,68	1,39	-0,005		Algorithm converged.	-0,075	0,064		0,981		Algorithm converged.	0,756	1,273	0,8851		1,019		Algorithm converged.	0,786	1,323
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	746	41,2	217	29,1	751	41,2	221	29,4	0,98		Algorithm converged.	0,79	1,23	-0,003		Algorithm converged.	-0,049	0,043		0,988		Algorithm converged.	0,844	1,157	0,8854	0,2702	1,012		Algorithm converged.	0,864	1,184
		Positive (ER and/or PgR positive)	786	43,4	211	26,8	838	46,0	200	23,9	1,17		Algorithm converged.	0,94	1,46	0,030		Algorithm converged.	-0,013	0,072		1,125		Algorithm converged.	0,952	1,329	0,1679		0,889		Algorithm converged.	0,752	1,051

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	211	11,7	45	21,3	223	12,2	55	24,7	0,83		Algorithm converged.	0,53	1,30	-0,033		Algorithm converged.	-0,112	0,046	0,865		Algorithm converged.	0,612	1,222	0,4104	0,6479	1,156		Algorithm converged.	0,818	1,635
		Western Europe	660	36,4	190	28,8	676	37,1	188	27,8	1,05		Algorithm converged.	0,83	1,33	0,010		Algorithm converged.	-0,039	0,058	1,035		Algorithm converged.	0,873	1,228	0,6918		0,966		Algorithm converged.	0,814	1,146
		Asia Pacific	461	25,5	135	29,3	485	26,6	128	26,4	1,15		Algorithm converged.	0,87	1,54	0,029		Algorithm converged.	-0,028	0,086	1,110		Algorithm converged.	0,904	1,363	0,3212		0,901		Algorithm converged.	0,734	1,107
		Latin America	38	2,1	12	31,6	42	2,3	9	21,4	1,69		Algorithm converged.	0,62	4,63	0,102		Algorithm converged.	-0,091	0,294	1,474		Algorithm converged.	0,700	3,103	0,3074		0,679		Algorithm converged.	0,322	1,429
		Other	162	8,9	46	28,4	163	8,9	41	25,2	1,18		Algorithm converged.	0,72	1,93	0,032		Algorithm converged.	-0,064	0,129	1,129		Algorithm converged.	0,787	1,619	0,5098		0,886		Algorithm converged.	0,618	1,270
	Protocol version	Protocol A	1047	57,8	290	27,7	1086	59,6	284	26,2	1,08		Algorithm converged.	0,89	1,31	0,015		Algorithm converged.	-0,022	0,053	1,059		Algorithm converged.	0,921	1,218	0,4206	0,9122	0,944		Algorithm converged.	0,821	1,086
		Protocol amendment B	485	26,8	138	28,5	503	27,6	137	27,2	1,06		Algorithm converged.	0,80	1,40	0,012		Algorithm converged.	-0,044	0,068	1,045		Algorithm converged.	0,855	1,277	0,6696		0,957		Algorithm converged.	0,783	1,170
	Nodal status	0 positive nodes	267	14,7	82	30,7	283	15,5	96	33,9	0,86		Algorithm converged.	0,60	1,24	-0,032		Algorithm converged.	-0,110	0,046	0,905		Algorithm converged.	0,710	1,154	0,4220	0,1666	1,105		Algorithm converged.	0,867	1,408
		>= 1 positive nodes	1265	69,9	346	27,4	1306	71,6	325	24,9	1,14		Algorithm converged.	0,95	1,36	0,025		Algorithm converged.	-0,009	0,059	1,099		Algorithm converged.	0,965	1,252	0,1547		0,910		Algorithm converged.	0,799	1,036
	Menopausal status at randomization	Premenopausal	748	41,3	199	26,6	796	43,7	194	24,4	1,12		Algorithm converged.	0,89	1,41	0,022		Algorithm converged.	-0,021	0,066	1,092		Algorithm converged.	0,920	1,295	0,3143	0,5381	0,916		Algorithm converged.	0,772	1,087
		Postmenopausal	780	43,1	228	29,2	785	43,1	226	28,8	1,02		Algorithm converged.	0,82	1,27	0,004		Algorithm converged.	-0,041	0,049	1,015		Algorithm converged.	0,870	1,186	0,8476		0,985		Algorithm converged.	0,843	1,150
		Unknown/Missing	4	0,2	1	25,0	8	0,4	1	12,5	2,33		Algorithm converged.	0,11	50,98	0,125		Algorithm converged.	-0,357	0,607	2,000		Algorithm converged.	0,164	24,328	0,5866		0,500		Algorithm converged.	0,041	6,082
	Age II	< 65	1352	74,7	370	27,4	1415	77,6	380	26,9	1,03		Algorithm converged.	0,87	1,21	0,005		Algorithm converged.	-0,028	0,038	1,019		Algorithm converged.	0,902	1,152	0,7621	0,1085	0,981		Algorithm converged.	0,868	1,109
		>= 65	180	9,9	58	32,2	174	9,5	41	23,6	1,54		Algorithm converged.	0,96	2,47	0,087		Algorithm converged.	-0,006	0,180	1,367		Algorithm converged.	0,972	1,924	0,0723		0,731		Algorithm converged.	0,520	1,029

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	7	25,9	22	1,2	7	31,8	0,75		Algorithm converged.	0,22	2,60	-0,059		Algorithm converged.	-0,314	0,196	0,815		Algorithm converged.	0,337	1,971	0,6496	0,7490	1,227		Algorithm converged.	0,507	2,969
		Grade 2	471	26,0	133	28,2	485	26,6	125	25,8	1,13		Algorithm converged.	0,85	1,51	0,025		Algorithm converged.	-0,032	0,081	1,096		Algorithm converged.	0,889	1,350	0,3910		0,913		Algorithm converged.	0,741	1,124
		Grade 3	975	53,8	268	27,5	1024	56,2	275	26,9	1,03		Algorithm converged.	0,85	1,26	0,006		Algorithm converged.	-0,033	0,045	1,024		Algorithm converged.	0,887	1,182	0,7509		0,977		Algorithm converged.	0,846	1,128
		Unevaluable/Unknown/Missing	59	3,3	20	33,9	58	3,2	14	24,1	1,61		Algorithm converged.	0,72	3,61	0,098		Algorithm converged.	-0,066	0,261	1,404		Algorithm converged.	0,787	2,505	0,2503		0,712		Algorithm converged.	0,399	1,270
	Type of surgery for primary tumor	Breast conserving surgery	604	33,4	191	31,6	600	32,9	179	29,8	1,09		Algorithm converged.	0,85	1,39	0,018		Algorithm converged.	-0,034	0,070	1,060		Algorithm converged.	0,894	1,256	0,5012	0,8883	0,943		Algorithm converged.	0,796	1,118
		Mastectomy	928	51,2	237	25,5	988	54,2	242	24,5	1,06		Algorithm converged.	0,86	1,30	0,010		Algorithm converged.	-0,028	0,049	1,043		Algorithm converged.	0,893	1,218	0,5976		0,959		Algorithm converged.	0,821	1,120
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	563	31,1	153	27,2	579	31,8	154	26,6	1,03		Algorithm converged.	0,79	1,34	0,006		Algorithm converged.	-0,046	0,057	1,022		Algorithm converged.	0,844	1,237	0,8256	0,6104	0,979		Algorithm converged.	0,808	1,185
		>= 2 - < 5 cm	844	46,6	240	28,4	859	47,1	234	27,2	1,06		Algorithm converged.	0,86	1,31	0,012		Algorithm converged.	-0,031	0,055	1,044		Algorithm converged.	0,896	1,216	0,5822		0,958		Algorithm converged.	0,822	1,116
		>= 5 cm	123	6,8	34	27,6	149	8,2	32	21,5	1,40		Algorithm converged.	0,80	2,44	0,062		Algorithm converged.	-0,041	0,165	1,287		Algorithm converged.	0,846	1,958	0,2384		0,777		Algorithm converged.	0,511	1,182
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1184	65,4	347	29,3	1201	65,9	319	26,6	1,15		Algorithm converged.	0,96	1,37	0,027		Algorithm converged.	-0,009	0,063	1,103		Algorithm converged.	0,970	1,255	0,1353	0,1278	0,906		Algorithm converged.	0,797	1,031
		No	348	19,2	81	23,3	388	21,3	102	26,3	0,85		Algorithm converged.	0,61	1,19	-0,030		Algorithm converged.	-0,092	0,032	0,885		Algorithm converged.	0,687	1,141	0,3462		1,129		Algorithm converged.	0,877	1,455
	Race	White	1012	55,9	270	26,7	1058	58,0	284	26,8	0,99		Algorithm converged.	0,82	1,20	-0,002		Algorithm converged.	-0,040	0,037	0,994		Algorithm converged.	0,862	1,146	0,9332	0,3308	1,006		Algorithm converged.	0,872	1,160

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	8	38,1	26	1,4	6	23,1	2,05		Algorithm converged.	0,58	7,29	0,150		Algorithm converged.	-0,113	0,414	1,651		Algorithm converged.	0,679	4,015	0,2689		0,606		Algorithm converged.	0,249	1,473
		Asian	448	24,7	132	29,5	457	25,1	119	26,0	1,19		Algorithm converged.	0,89	1,59	0,034		Algorithm converged.	-0,024	0,093	1,132		Algorithm converged.	0,917	1,397	0,2504		0,884		Algorithm converged.	0,716	1,091
		Other	47	2,6	18	38,3	47	2,6	12	25,5	1,81		Algorithm converged.	0,75	4,37	0,128		Algorithm converged.	-0,059	0,314	1,500		Algorithm converged.	0,816	2,756	0,1914		0,667		Algorithm converged.	0,363	1,225
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1357	74,9	295	21,7	1320	72,4	320	24,2	0,87		Algorithm converged.	0,72	1,04	-0,025		Algorithm converged.	-0,057	0,007	0,897		Algorithm converged.	0,780	1,030	0,1240		1,115		Algorithm converged.	0,971	1,281
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	12	27,3	35	1,9	14	40,0	0,56		Algorithm converged.	0,22	1,45	-0,127		Algorithm converged.	-0,336	0,082	0,682		Algorithm converged.	0,363	1,281	0,2338	0,4862	1,467		Algorithm converged.	0,781	2,755
		0 positive nodes, tumor > 1 cm	213	11,8	46	21,6	222	12,2	64	28,8	0,68		Algorithm converged.	0,44	1,05	-0,072		Algorithm converged.	-0,154	0,009	0,749		Algorithm converged.	0,539	1,041	0,0852		1,335		Algorithm converged.	0,961	1,855
		1-3 positive nodes	689	38,0	152	22,1	652	35,8	149	22,9	0,96		Algorithm converged.	0,74	1,24	-0,008		Algorithm converged.	-0,053	0,037	0,965		Algorithm converged.	0,791	1,178	0,7283		1,036		Algorithm converged.	0,849	1,264
		>= 4 positive nodes	411	22,7	85	20,7	411	22,5	93	22,6	0,89		Algorithm converged.	0,64	1,24	-0,019		Algorithm converged.	-0,076	0,037	0,914		Algorithm converged.	0,704	1,186	0,4984		1,094		Algorithm converged.	0,843	1,420
	Adjuvant chemotherapy regimen	Anthracycline	1082	59,7	238	22,0	1059	58,1	250	23,6	0,91		Algorithm converged.	0,75	1,12	-0,016		Algorithm converged.	-0,052	0,019	0,932		Algorithm converged.	0,797	1,089	0,3745	0,2845	1,073		Algorithm converged.	0,918	1,254
		Non-anthracycline	275	15,2	57	20,7	261	14,3	70	26,8	0,71		Algorithm converged.	0,48	1,06	-0,061		Algorithm converged.	-0,133	0,011	0,773		Algorithm converged.	0,569	1,049	0,0987		1,294		Algorithm converged.	0,953	1,757
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	663	36,6	145	21,9	642	35,2	170	26,5	0,78		Algorithm converged.	0,60	1,00	-0,046		Algorithm converged.	-0,093	0,000	0,826		Algorithm converged.	0,681	1,002	0,0523	0,2363	1,211		Algorithm converged.	0,998	1,469

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	694	38,3	150	21,6	678	37,2	150	22,1	0,97		Algorithm converged.	0,75	1,25	-0,005		Algorithm converged.	-0,049	0,039	0,977		Algorithm converged.	0,800	1,193	0,8192		1,024		Algorithm converged.	0,838	1,250
	Geographical region II	USA/Canada	177	9,8	31	17,5	155	8,5	25	16,1	1,10		Algorithm converged.	0,62	1,97	0,014		Algorithm converged.	-0,067	0,094	1,086		Algorithm converged.	0,671	1,756	0,7369	0,8478	0,921		Algorithm converged.	0,569	1,489
		Western Europe	585	32,3	124	21,2	571	31,3	143	25,0	0,81		Algorithm converged.	0,61	1,06	-0,038		Algorithm converged.	-0,087	0,010	0,846		Algorithm converged.	0,685	1,045	0,1214		1,182		Algorithm converged.	0,957	1,459
		Asia Pacific	415	22,9	104	25,1	427	23,4	112	26,2	0,94		Algorithm converged.	0,69	1,28	-0,012		Algorithm converged.	-0,071	0,047	0,955		Algorithm converged.	0,759	1,203	0,6978		1,047		Algorithm converged.	0,831	1,318
		Latin America	34	1,9	7	20,6	36	2,0	8	22,2	0,91		Algorithm converged.	0,29	2,85	-0,016		Algorithm converged.	-0,208	0,176	0,926		Algorithm converged.	0,377	2,278	0,8678		1,079		Algorithm converged.	0,439	2,654
		Other	146	8,1	29	19,9	131	7,2	32	24,4	0,77		Algorithm converged.	0,43	1,36	-0,046		Algorithm converged.	-0,144	0,052	0,813		Algorithm converged.	0,522	1,267	0,3609		1,230		Algorithm converged.	0,789	1,917
	Protocol version	Protocol A	953	52,6	196	20,6	912	50,0	226	24,8	0,79		Algorithm converged.	0,63	0,98	-0,042		Algorithm converged.	-0,080	-0,004	0,830		Algorithm converged.	0,701	0,982	0,0300	0,1032	1,205		Algorithm converged.	1,018	1,426
		Protocol amendment B	404	22,3	99	24,5	408	22,4	94	23,0	1,08		Algorithm converged.	0,78	1,50	0,015		Algorithm converged.	-0,044	0,073	1,064		Algorithm converged.	0,831	1,361	0,6238		0,940		Algorithm converged.	0,735	1,203
	Nodal status	0 positive nodes	257	14,2	58	22,6	257	14,1	78	30,4	0,67		Algorithm converged.	0,45	0,99	-0,078		Algorithm converged.	-0,154	-0,002	0,744		Algorithm converged.	0,555	0,996	0,0472	0,1531	1,345		Algorithm converged.	1,004	1,802
		>= 1 positive nodes	1100	60,7	237	21,5	1063	58,3	242	22,8	0,93		Algorithm converged.	0,76	1,14	-0,012		Algorithm converged.	-0,047	0,023	0,946		Algorithm converged.	0,808	1,108	0,4945		1,057		Algorithm converged.	0,902	1,238
	Menopausal status at randomization	Premenopausal	659	36,4	143	21,7	657	36,0	152	23,1	0,92		Algorithm converged.	0,71	1,19	-0,014		Algorithm converged.	-0,059	0,031	0,938		Algorithm converged.	0,767	1,147	0,5324	0,5500	1,066		Algorithm converged.	0,872	1,304
		Postmenopausal	694	38,3	152	21,9	657	36,0	167	25,4	0,82		Algorithm converged.	0,64	1,06	-0,035		Algorithm converged.	-0,081	0,010	0,862		Algorithm converged.	0,711	1,044	0,1287		1,161		Algorithm converged.	0,958	1,406

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	6	0,3	1	16,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1204	66,5	257	21,3	1179	64,7	281	23,8	0,87		Algorithm converged.	0,72	1,05	-0,025		Algorithm converged.	-0,058	0,009	0,896		Algorithm converged.	0,772	1,039	0,1467	0,9901	1,117		Algorithm converged.	0,962	1,296
		>= 65	153	8,4	38	24,8	141	7,7	39	27,7	0,86		Algorithm converged.	0,51	1,45	-0,028		Algorithm converged.	-0,129	0,072	0,898		Algorithm converged.	0,612	1,318	0,5824		1,114		Algorithm converged.	0,759	1,635
	Histological grade	Grade 1	26	1,4	3	11,5	20	1,1	5	25,0	0,39		Algorithm converged.	0,08	1,89	-0,135		Algorithm converged.	-0,361	0,091	0,462		Algorithm converged.	0,125	1,706	0,2464	-	2,167		Algorithm converged.	0,586	8,008
		Grade 2	426	23,5	92	21,6	405	22,2	93	23,0	0,92		Algorithm converged.	0,67	1,28	-0,014		Algorithm converged.	-0,070	0,043	0,940		Algorithm converged.	0,729	1,213	0,6360		1,063		Algorithm converged.	0,825	1,371
		Grade 3	856	47,3	190	22,2	846	46,4	207	24,5	0,88		Algorithm converged.	0,70	1,10	-0,023		Algorithm converged.	-0,063	0,017	0,907		Algorithm converged.	0,763	1,078	0,2681		1,102		Algorithm converged.	0,928	1,310
		Unevaluable/Unknown/Missing	49	2,7	10	20,4	49	2,7	15	30,6	0,58		Algorithm converged.	0,23	1,46	-0,102		Algorithm converged.	-0,273	0,069	0,667		Algorithm converged.	0,333	1,336	0,2531		1,500		Algorithm converged.	0,748	3,006
	Type of surgery for primary tumor	Breast conserving surgery	543	30,0	125	23,0	517	28,4	137	26,5	0,83		Algorithm converged.	0,63	1,10	-0,035		Algorithm converged.	-0,087	0,017	0,869		Algorithm converged.	0,704	1,072	0,1899	0,7082	1,151		Algorithm converged.	0,933	1,421
		Mastectomy	814	44,9	170	20,9	803	44,0	183	22,8	0,89		Algorithm converged.	0,71	1,13	-0,019		Algorithm converged.	-0,059	0,021	0,916		Algorithm converged.	0,762	1,102	0,3541		1,091		Algorithm converged.	0,907	1,312
	Tumor size	0 - < 2 cm	512	28,3	93	18,2	489	26,8	123	25,2	0,66		Algorithm converged.	0,49	0,89	-0,070		Algorithm converged.	-0,121	-0,019	0,722		Algorithm converged.	0,569	0,917	0,0076	0,0201	1,385		Algorithm converged.	1,090	1,759

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	743	41,0	188	25,3	716	39,3	172	24,0	1,07		Algorithm converged.	0,84	1,36	0,013		Algorithm converged.	-0,031	0,057	1,053		Algorithm converged.	0,880	1,260	0,5708		0,949		Algorithm converged.	0,793	1,136
		>= 5 cm	100	5,5	13	13,0	113	6,2	24	21,2	0,55		Algorithm converged.	0,27	1,16	-0,082		Algorithm converged.	-0,183	0,018	0,612		Algorithm converged.	0,330	1,137	0,1201		1,634		Algorithm converged.	0,880	3,034
		Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Loco-regional radiotherapy	Yes	1036	57,2	233	22,5	1006	55,2	242	24,1	0,92		Algorithm converged.	0,75	1,12	-0,016		Algorithm converged.	-0,052	0,021	0,935		Algorithm converged.	0,799	1,095	0,4027	0,2787	1,070		Algorithm converged.	0,914	1,252
		No	321	17,7	62	19,3	314	17,2	78	24,8	0,72		Algorithm converged.	0,50	1,06	-0,055		Algorithm converged.	-0,120	0,009	0,778		Algorithm converged.	0,579	1,044	0,0945		1,286		Algorithm converged.	0,958	1,727
	Race	White	891	49,2	185	20,8	873	47,9	202	23,1	0,87		Algorithm converged.	0,69	1,09	-0,024		Algorithm converged.	-0,062	0,015	0,897		Algorithm converged.	0,752	1,070	0,2284	-	1,114		Algorithm converged.	0,934	1,329
		Black	18	1,0	2	11,1	19	1,0	5	26,3	0,35		Algorithm converged.	0,06	2,10	-0,152		Algorithm converged.	-0,398	0,093	0,422		Algorithm converged.	0,093	1,907	0,2624		2,368		Algorithm converged.	0,524	10,698
		Asian	399	22,0	98	24,6	394	21,6	106	26,9	0,88		Algorithm converged.	0,64	1,22	-0,023		Algorithm converged.	-0,084	0,037	0,913		Algorithm converged.	0,720	1,157	0,4509		1,095		Algorithm converged.	0,864	1,388
		Other	44	2,4	10	22,7	33	1,8	7	21,2	1,09		Algorithm converged.	0,37	3,26	0,015		Algorithm converged.	-0,171	0,202	1,071		Algorithm converged.	0,456	2,517	0,8742		0,933		Algorithm converged.	0,397	2,192
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_GLHST_W15_SG.xls
26OCT2020 15:57

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Physical Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1543	85,2	203	13,2	1597	87,6	196	12,3	1,08		Algorithm converged.	0,88	1,34	0,009		Algorithm converged.	-0,014	0,032	1,072		Algorithm converged.	0,892	1,288	0,4577		0,933		Algorithm converged.	0,777	1,121
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	2	4,7	35	1,9	2	5,7	0,80		Algorithm converged.	0,11	6,02	-0,011		Algorithm converged.	-0,110	0,089	0,814		Algorithm converged.	0,121	5,488	0,8326	-	1,229		Algorithm converged.	0,182	8,284
		0 positive nodes, tumor > 1 cm	225	12,4	33	14,7	248	13,6	27	10,9	1,41		Algorithm converged.	0,82	2,42	0,038		Algorithm converged.	-0,023	0,098	1,347		Algorithm converged.	0,837	2,167	0,2193		0,742		Algorithm converged.	0,461	1,194
		1-3 positive nodes	771	42,6	107	13,9	796	43,7	103	12,9	1,08		Algorithm converged.	0,81	1,45	0,009		Algorithm converged.	-0,024	0,043	1,073		Algorithm converged.	0,834	1,380	0,5857		0,932		Algorithm converged.	0,725	1,199
		>= 4 positive nodes	504	27,8	61	12,1	518	28,4	64	12,4	0,98		Algorithm converged.	0,67	1,42	-0,003		Algorithm converged.	-0,043	0,038	0,980		Algorithm converged.	0,705	1,361	0,9022		1,021		Algorithm converged.	0,735	1,418
	Adjuvant chemotherapy regimen	Anthracycline	1235	68,2	162	13,1	1281	70,3	163	12,7	1,04		Algorithm converged.	0,82	1,31	0,004		Algorithm converged.	-0,022	0,030	1,031		Algorithm converged.	0,842	1,263	0,7689	0,3809	0,970		Algorithm converged.	0,792	1,188
		Non-anthracycline	308	17,0	41	13,3	316	17,3	33	10,4	1,32		Algorithm converged.	0,81	2,15	0,029		Algorithm converged.	-0,022	0,079	1,275		Algorithm converged.	0,829	1,961	0,2693		0,785		Algorithm converged.	0,510	1,207
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	752	41,5	95	12,6	754	41,4	86	11,4	1,12		Algorithm converged.	0,82	1,53	0,012		Algorithm converged.	-0,021	0,045	1,108		Algorithm converged.	0,842	1,456	0,4643	0,7624	0,903		Algorithm converged.	0,687	1,187
		Positive (ER and/or PgR positive)	791	43,7	108	13,7	843	46,2	110	13,0	1,05		Algorithm converged.	0,79	1,40	0,006		Algorithm converged.	-0,027	0,039	1,046		Algorithm converged.	0,817	1,340	0,7193		0,956		Algorithm converged.	0,746	1,224

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	215	11,9	28	13,0	224	12,3	27	12,1	1,09		Algorithm converged.	0,62	1,92	0,010		Algorithm converged.	-0,052	0,072		1,080		Algorithm converged.	0,659	1,771	0,7591	-		0,926		Algorithm converged.	0,565	1,517
		Western Europe	667	36,8	117	17,5	680	37,3	109	16,0	1,11		Algorithm converged.	0,84	1,48	0,015		Algorithm converged.	-0,025	0,055		1,094		Algorithm converged.	0,862	1,388	0,4580			0,914		Algorithm converged.	0,720	1,159
		Asia Pacific	461	25,5	38	8,2	488	26,8	30	6,1	1,37		Algorithm converged.	0,83	2,25	0,021		Algorithm converged.	-0,012	0,054		1,341		Algorithm converged.	0,845	2,127	0,2128			0,746		Algorithm converged.	0,470	1,183
		Latin America	38	2,1	3	7,9	42	2,3	3	7,1	1,11		Algorithm converged.	0,21	5,88	0,008		Algorithm converged.	-0,108	0,123		1,105		Algorithm converged.	0,237	5,150	0,8986			0,905		Algorithm converged.	0,194	4,216
		Other	162	8,9	17	10,5	163	8,9	27	16,6	0,59		Algorithm converged.	0,31	1,13	-0,061		Algorithm converged.	-0,135	0,013		0,634		Algorithm converged.	0,360	1,116	0,1143			1,578		Algorithm converged.	0,896	2,782
	Protocol version	Protocol A	1053	58,1	131	12,4	1092	59,9	127	11,6	1,08		Algorithm converged.	0,83	1,40	0,008		Algorithm converged.	-0,019	0,036		1,070		Algorithm converged.	0,851	1,345	0,5640	0,9782		0,935		Algorithm converged.	0,744	1,175
		Protocol amendment B	490	27,1	72	14,7	505	27,7	69	13,7	1,09		Algorithm converged.	0,76	1,55	0,010		Algorithm converged.	-0,033	0,054		1,075		Algorithm converged.	0,792	1,460	0,6413			0,930		Algorithm converged.	0,685	1,263
	Nodal status	0 positive nodes	268	14,8	35	13,1	283	15,5	29	10,2	1,32		Algorithm converged.	0,78	2,22	0,028		Algorithm converged.	-0,026	0,082		1,274		Algorithm converged.	0,802	2,025	0,3045	0,4214		0,785		Algorithm converged.	0,494	1,247
		>= 1 positive nodes	1275	70,4	168	13,2	1314	72,1	167	12,7	1,04		Algorithm converged.	0,83	1,31	0,005		Algorithm converged.	-0,021	0,031		1,037		Algorithm converged.	0,849	1,266	0,7233			0,965		Algorithm converged.	0,790	1,178
	Menopausal status at randomization	Premenopausal	754	41,6	65	8,6	798	43,8	84	10,5	0,80		Algorithm converged.	0,57	1,13	-0,019		Algorithm converged.	-0,048	0,010		0,819		Algorithm converged.	0,602	1,114	0,2039	0,0362		1,221		Algorithm converged.	0,897	1,662
		Postmenopausal	785	43,3	137	17,5	791	43,4	112	14,2	1,28		Algorithm converged.	0,98	1,68	0,033		Algorithm converged.	-0,003	0,069		1,233		Algorithm converged.	0,980	1,550	0,0739			0,811		Algorithm converged.	0,645	1,020

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	1	25,0	8	0,4	0	0,0	NE		Algorithm converged.	NE	NE	0,262	*	WARNING: The relative Hessian convergence criterion of 3.5555052554 is greater than the limit of 0.0001. The convergence is questionable.	-0,557	1,082	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Age II	< 65	1362	75,2	151	11,1	1422	78,0	169	11,9	0,92		Algorithm converged.	0,73	1,17	-0,008		Algorithm converged.	-0,032	0,016	0,933		Algorithm converged.	0,759	1,147	0,5095	0,0027	1,072		Algorithm converged.	0,872	1,318
		>= 65	181	10,0	52	28,7	175	9,6	27	15,4	2,21		Algorithm converged.	1,31	3,72	0,133		Algorithm converged.	0,048	0,218	1,862		Algorithm converged.	1,228	2,822	0,0034		0,537		Algorithm converged.	0,354	0,814
	Histological grade	Grade 1	27	1,5	4	14,8	21	1,2	2	9,5	1,65		Algorithm converged.	0,27	10,02	0,053		Algorithm converged.	-0,131	0,237	1,556		Algorithm converged.	0,314	7,695	0,5880	-	0,643		Algorithm converged.	0,130	3,180
		Grade 2	473	26,1	68	14,4	487	26,7	54	11,1	1,35		Algorithm converged.	0,92	1,97	0,033		Algorithm converged.	-0,009	0,075	1,297		Algorithm converged.	0,928	1,811	0,1276		0,771		Algorithm converged.	0,552	1,077
		Grade 3	984	54,3	124	12,6	1030	56,5	134	13,0	0,96		Algorithm converged.	0,74	1,25	-0,004		Algorithm converged.	-0,033	0,025	0,969		Algorithm converged.	0,771	1,217	0,7842		1,032		Algorithm converged.	0,822	1,297
		Unevaluable/Unknown/Missing	59	3,3	7	11,9	59	3,2	6	10,2	1,19		Algorithm converged.	0,37	3,78	0,017		Algorithm converged.	-0,096	0,130	1,167		Algorithm converged.	0,417	3,265	0,7690		0,857		Algorithm converged.	0,306	2,398
	Type of surgery for primary tumor	Breast conserving surgery	609	33,6	107	17,6	601	33,0	96	16,0	1,12		Algorithm converged.	0,83	1,52	0,016		Algorithm converged.	-0,026	0,058	1,100		Algorithm converged.	0,855	1,414	0,4578	0,7368	0,909		Algorithm converged.	0,707	1,169

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Mastectomy	934	51,6	96	10,3	995	54,6	99	9,9	1,04		Algorithm converged.	0,77	1,39	0,003		Algorithm converged.	-0,024	0,030	1,033		Algorithm converged.	0,792	1,348	0,8109		0,968		Algorithm converged.	0,742	1,263
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	569	31,4	76	13,4	581	31,9	74	12,7	1,06		Algorithm converged.	0,75	1,49	0,006		Algorithm converged.	-0,033	0,045	1,049		Algorithm converged.	0,778	1,413	0,7549	0,7981	0,954		Algorithm converged.	0,707	1,285
		>= 2 - < 5 cm	849	46,9	114	13,4	864	47,4	104	12,0	1,13		Algorithm converged.	0,85	1,51	0,014		Algorithm converged.	-0,018	0,045	1,116		Algorithm converged.	0,870	1,430	0,3882		0,896		Algorithm converged.	0,699	1,149
		>= 5 cm	123	6,8	13	10,6	150	8,2	18	12,0	0,87		Algorithm converged.	0,41	1,85	-0,014		Algorithm converged.	-0,090	0,061	0,881		Algorithm converged.	0,450	1,725	0,7113		1,135		Algorithm converged.	0,580	2,224
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1192	65,8	166	13,9	1207	66,2	155	12,8	1,10		Algorithm converged.	0,87	1,39	0,011		Algorithm converged.	-0,016	0,038	1,084		Algorithm converged.	0,885	1,330	0,4355	0,7422	0,922		Algorithm converged.	0,752	1,131
		No	351	19,4	37	10,5	390	21,4	41	10,5	1,00		Algorithm converged.	0,63	1,60	0,000		Algorithm converged.	-0,044	0,045	1,003		Algorithm converged.	0,659	1,527	0,9899		0,997		Algorithm converged.	0,655	1,518
	Race	White	1021	56,4	159	15,6	1062	58,3	163	15,3	1,02		Algorithm converged.	0,80	1,29	0,002		Algorithm converged.	-0,029	0,033	1,015		Algorithm converged.	0,830	1,240	0,8873	-	0,986		Algorithm converged.	0,806	1,205
		Black	21	1,2	4	19,0	27	1,5	4	14,8	1,35		Algorithm converged.	0,30	6,19	0,042		Algorithm converged.	-0,173	0,257	1,286		Algorithm converged.	0,364	4,547	0,6966		0,778		Algorithm converged.	0,220	2,751
		Asian	450	24,8	36	8,0	460	25,2	26	5,7	1,45		Algorithm converged.	0,86	2,45	0,023		Algorithm converged.	-0,009	0,056	1,415		Algorithm converged.	0,869	2,304	0,1624		0,707		Algorithm converged.	0,434	1,150
		Other	47	2,6	3	6,4	47	2,6	3	6,4	1,00		Algorithm converged.	0,19	5,23	0,000		Algorithm converged.	-0,099	0,099	1,000		Algorithm converged.	0,213	4,704	1,0000		1,000		Algorithm converged.	0,213	4,704

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1363	75,3	121	8,9	1329	72,9	111	8,4	1,07		Algorithm converged.	0,82	1,40	0,005		Algorithm converged.	-0,016	0,026	1,063		Algorithm converged.	0,831	1,360	0,6273		0,941		Algorithm converged.	0,735	1,204
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	5	11,4	35	1,9	1	2,9	4,36		Algorithm converged.	0,49	39,17	0,085		Algorithm converged.	-0,024	0,194	3,977		Algorithm converged.	0,487	32,500	0,1977	-	0,251		Algorithm converged.	0,031	2,055
		0 positive nodes, tumor > 1 cm	213	11,8	22	10,3	222	12,2	18	8,1	1,31		Algorithm converged.	0,68	2,51	0,022		Algorithm converged.	-0,032	0,077	1,274		Algorithm converged.	0,703	2,307	0,4244		0,785		Algorithm converged.	0,433	1,422
		1-3 positive nodes	694	38,3	63	9,1	658	36,1	49	7,4	1,24		Algorithm converged.	0,84	1,83	0,016		Algorithm converged.	-0,013	0,046	1,219		Algorithm converged.	0,852	1,743	0,2779		0,820		Algorithm converged.	0,574	1,173
		>= 4 positive nodes	412	22,7	31	7,5	414	22,7	43	10,4	0,70		Algorithm converged.	0,43	1,14	-0,029		Algorithm converged.	-0,068	0,010	0,724		Algorithm converged.	0,466	1,126	0,1521		1,380		Algorithm converged.	0,888	2,146
	Adjuvant chemotherapy regimen	Anthracycline	1088	60,1	94	8,6	1068	58,6	89	8,3	1,04		Algorithm converged.	0,77	1,41	0,003		Algorithm converged.	-0,020	0,027	1,037		Algorithm converged.	0,786	1,368	0,7986	0,7053	0,965		Algorithm converged.	0,731	1,273
		Non-anthracycline	275	15,2	27	9,8	261	14,3	22	8,4	1,18		Algorithm converged.	0,66	2,13	0,014		Algorithm converged.	-0,035	0,063	1,165		Algorithm converged.	0,681	1,992	0,5776		0,859		Algorithm converged.	0,502	1,469
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	665	36,7	57	8,6	645	35,4	46	7,1	1,22		Algorithm converged.	0,81	1,83	0,014		Algorithm converged.	-0,015	0,044	1,202		Algorithm converged.	0,828	1,745	0,3340	0,3860	0,832		Algorithm converged.	0,573	1,208

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	698	38,5	64	9,2	684	37,5	65	9,5	0,96		Algorithm converged.	0,67	1,38	-0,003		Algorithm converged.	-0,034	0,027	0,965		Algorithm converged.	0,695	1,340	0,8311		1,036		Algorithm converged.	0,746	1,440
	Geographical region II	USA/Canada	179	9,9	21	11,7	155	8,5	12	7,7	1,58		Algorithm converged.	0,75	3,33	0,040		Algorithm converged.	-0,023	0,103	1,515		Algorithm converged.	0,771	2,979	0,2281	-	0,660		Algorithm converged.	0,336	1,297
		Western Europe	588	32,5	66	11,2	579	31,8	58	10,0	1,14		Algorithm converged.	0,78	1,65	0,012		Algorithm converged.	-0,023	0,047	1,121		Algorithm converged.	0,803	1,564	0,5038		0,892		Algorithm converged.	0,639	1,246
		Asia Pacific	415	22,9	21	5,1	428	23,5	22	5,1	0,98		Algorithm converged.	0,53	1,82	-0,001		Algorithm converged.	-0,031	0,029	0,984		Algorithm converged.	0,550	1,763	0,9579		1,016		Algorithm converged.	0,567	1,819
		Latin America	34	1,9	3	8,8	36	2,0	4	11,1	0,77		Algorithm converged.	0,16	3,74	-0,023		Algorithm converged.	-0,163	0,117	0,794		Algorithm converged.	0,192	3,291	0,7506		1,259		Algorithm converged.	0,304	5,218
		Other	147	8,1	10	6,8	131	7,2	15	11,5	0,56		Algorithm converged.	0,24	1,30	-0,046		Algorithm converged.	-0,115	0,022	0,594		Algorithm converged.	0,277	1,276	0,1820		1,683		Algorithm converged.	0,783	3,616
	Protocol version	Protocol A	958	52,9	82	8,6	919	50,4	79	8,6	1,00		Algorithm converged.	0,72	1,38	0,000		Algorithm converged.	-0,026	0,025	0,996		Algorithm converged.	0,741	1,338	0,9773	0,4321	1,004		Algorithm converged.	0,747	1,349
		Protocol amendment B	405	22,4	39	9,6	410	22,5	32	7,8	1,26		Algorithm converged.	0,77	2,05	0,018		Algorithm converged.	-0,020	0,057	1,234		Algorithm converged.	0,789	1,929	0,3568		0,811		Algorithm converged.	0,518	1,267
	Nodal status	0 positive nodes	257	14,2	27	10,5	257	14,1	19	7,4	1,47		Algorithm converged.	0,80	2,72	0,031		Algorithm converged.	-0,018	0,080	1,421		Algorithm converged.	0,811	2,490	0,2195	0,2542	0,704		Algorithm converged.	0,402	1,233
		>= 1 positive nodes	1106	61,1	94	8,5	1072	58,8	92	8,6	0,99		Algorithm converged.	0,73	1,34	-0,001		Algorithm converged.	-0,024	0,023	0,990		Algorithm converged.	0,752	1,304	0,9448		1,010		Algorithm converged.	0,767	1,329
	Menopausal status at randomization	Premenopausal	663	36,6	42	6,3	661	36,3	42	6,4	1,00		Algorithm converged.	0,64	1,55	0,000		Algorithm converged.	-0,026	0,026	0,997		Algorithm converged.	0,659	1,508	0,9886	0,7364	1,003		Algorithm converged.	0,663	1,517
		Postmenopausal	696	38,4	79	11,4	662	36,3	69	10,4	1,10		Algorithm converged.	0,78	1,55	0,009		Algorithm converged.	-0,024	0,042	1,089		Algorithm converged.	0,803	1,477	0,5837		0,918		Algorithm converged.	0,677	1,246
		Unknown/Missing	4	0,2	0	0,0	6	0,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Age II	< 65	1210	66,8	94	7,8	1187	65,1	96	8,1	0,96		Algorithm converged.	0,71	1,29	-0,003		Algorithm converged.	-0,025	0,018	0,961		Algorithm converged.	0,731	1,262	0,7725	0,0884	1,041		Algorithm converged.	0,792	1,368
		>= 65	153	8,4	27	17,6	142	7,8	15	10,6	1,81		Algorithm converged.	0,92	3,57	0,071		Algorithm converged.	-0,008	0,150	1,671		Algorithm converged.	0,928	3,009	0,0874		0,599		Algorithm converged.	0,332	1,078
	Histological grade	Grade 1	26	1,4	5	19,2	20	1,1	2	10,0	2,14		Algorithm converged.	0,37	12,41	0,092		Algorithm converged.	-0,108	0,293	1,923		Algorithm converged.	0,415	8,905	0,4030	-	0,520		Algorithm converged.	0,112	2,408
		Grade 2	428	23,6	33	7,7	407	22,3	32	7,9	0,98		Algorithm converged.	0,59	1,62	-0,002		Algorithm converged.	-0,038	0,035	0,981		Algorithm converged.	0,615	1,564	0,9346		1,020		Algorithm converged.	0,639	1,627
		Grade 3	860	47,5	81	9,4	851	46,7	74	8,7	1,09		Algorithm converged.	0,78	1,52	0,007		Algorithm converged.	-0,020	0,034	1,083		Algorithm converged.	0,802	1,463	0,6025		0,923		Algorithm converged.	0,684	1,247
		Unevaluable/Unknown/Missing	49	2,7	2	4,1	51	2,8	3	5,9	0,68		Algorithm converged.	0,11	4,26	-0,018		Algorithm converged.	-0,103	0,067	0,694		Algorithm converged.	0,121	3,976	0,6816		1,441		Algorithm converged.	0,252	8,258
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	58	10,6	521	28,6	50	9,6	1,12		Algorithm converged.	0,75	1,66	0,010		Algorithm converged.	-0,026	0,046	1,105		Algorithm converged.	0,772	1,582	0,5858	0,7586	0,905		Algorithm converged.	0,632	1,296
		Mastectomy	816	45,1	63	7,7	808	44,3	61	7,5	1,02		Algorithm converged.	0,71	1,48	0,002		Algorithm converged.	-0,024	0,028	1,023		Algorithm converged.	0,729	1,434	0,8967		0,978		Algorithm converged.	0,697	1,372
	Tumor size	0 - < 2 cm	516	28,5	45	8,7	491	26,9	38	7,7	1,14		Algorithm converged.	0,73	1,79	0,010		Algorithm converged.	-0,024	0,044	1,127		Algorithm converged.	0,745	1,704	0,5716	0,9432	0,887		Algorithm converged.	0,587	1,342
		>= 2 - < 5 cm	745	41,1	67	9,0	722	39,6	63	8,7	1,03		Algorithm converged.	0,72	1,48	0,003		Algorithm converged.	-0,026	0,032	1,031		Algorithm converged.	0,742	1,431	0,8570		0,970		Algorithm converged.	0,699	1,347
		>= 5 cm	100	5,5	9	9,0	114	6,3	10	8,8	1,03		Algorithm converged.	0,40	2,64	0,002		Algorithm converged.	-0,074	0,079	1,026		Algorithm converged.	0,434	2,424	0,9533		0,975		Algorithm converged.	0,413	2,302
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1042	57,5	94	9,0	1014	55,6	90	8,9	1,02		Algorithm converged.	0,75	1,38	0,001		Algorithm converged.	-0,023	0,026	1,016		Algorithm converged.	0,771	1,339	0,9081	0,4890	0,984		Algorithm converged.	0,747	1,296
		No	321	17,7	27	8,4	315	17,3	21	6,7	1,29		Algorithm converged.	0,71	2,33	0,017		Algorithm converged.	-0,024	0,058	1,262		Algorithm converged.	0,729	2,184	0,4063		0,793		Algorithm converged.	0,458	1,372

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Race	White	896	49,5	94	10,5	881	48,3	86	9,8	1,08		Algorithm converged.	0,80	1,47	0,007		Algorithm converged.	-0,021	0,035	1,075		Algorithm converged.	0,814	1,418	0,6105	-	0,930		Algorithm converged.	0,705	1,228
		Black	18	1,0	2	11,1	19	1,0	5	26,3	0,35		Algorithm converged.	0,06	2,10	-0,152		Algorithm converged.	-0,398	0,093	0,422		Algorithm converged.	0,093	1,907	0,2624		2,368		Algorithm converged.	0,524	10,698
		Asian	400	22,1	20	5,0	395	21,7	17	4,3	1,17		Algorithm converged.	0,60	2,27	0,007		Algorithm converged.	-0,022	0,036	1,162		Algorithm converged.	0,618	2,184	0,6416		0,861		Algorithm converged.	0,458	1,618
		Other	44	2,4	4	9,1	33	1,8	3	9,1	1,00		Algorithm converged.	0,21	4,81	0,000		Algorithm converged.	-0,130	0,130	1,000		Algorithm converged.	0,240	4,167	1,0000		1,000		Algorithm converged.	0,240	4,167
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC01_W15_SG.xls
26OCT2020 15:35

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Role Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1540	85,0	383	24,9	1594	87,4	368	23,1	1,10		Algorithm converged.	0,94	1,30	0,018		Algorithm converged.	-0,012	0,048	1,077		Algorithm converged.	0,951	1,220	0,2424		0,928		Algorithm converged.	0,819	1,052
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	6	14,0	35	1,9	5	14,3	0,97		Algorithm converged.	0,27	3,50	-0,003		Algorithm converged.	-0,159	0,152	0,977		Algorithm converged.	0,325	2,934	0,9665	0,9339	1,024		Algorithm converged.	0,341	3,075
		0 positive nodes, tumor > 1 cm	223	12,3	52	23,3	246	13,5	57	23,2	1,01		Algorithm converged.	0,66	1,55	0,001		Algorithm converged.	-0,075	0,078	1,006		Algorithm converged.	0,724	1,399	0,9698		0,994		Algorithm converged.	0,715	1,381
		1-3 positive nodes	771	42,6	204	26,5	796	43,7	188	23,6	1,16		Algorithm converged.	0,93	1,46	0,028		Algorithm converged.	-0,014	0,071	1,120		Algorithm converged.	0,944	1,330	0,1946		0,893		Algorithm converged.	0,752	1,060
		>= 4 positive nodes	503	27,8	121	24,1	517	28,4	118	22,8	1,07		Algorithm converged.	0,80	1,43	0,012		Algorithm converged.	-0,040	0,064	1,054		Algorithm converged.	0,844	1,316	0,6425		0,949		Algorithm converged.	0,760	1,185
	Adjuvant chemotherapy regimen	Anthracycline	1232	68,0	312	25,3	1278	70,1	298	23,3	1,12		Algorithm converged.	0,93	1,34	0,020		Algorithm converged.	-0,014	0,054	1,086		Algorithm converged.	0,946	1,247	0,2414	0,7945	0,921		Algorithm converged.	0,802	1,057
		Non-anthracycline	308	17,0	71	23,1	316	17,3	70	22,2	1,05		Algorithm converged.	0,72	1,53	0,009		Algorithm converged.	-0,057	0,075	1,041		Algorithm converged.	0,778	1,391	0,7881		0,961		Algorithm converged.	0,719	1,285
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	749	41,4	188	25,1	752	41,3	171	22,7	1,14		Algorithm converged.	0,90	1,44	0,024		Algorithm converged.	-0,020	0,067	1,104		Algorithm converged.	0,921	1,322	0,2841	0,7153	0,906		Algorithm converged.	0,756	1,085
		Positive (ER and/or PgR positive)	791	43,7	195	24,7	842	46,2	197	23,4	1,07		Algorithm converged.	0,85	1,34	0,013		Algorithm converged.	-0,029	0,054	1,054		Algorithm converged.	0,887	1,252	0,5527		0,949		Algorithm converged.	0,799	1,128

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	214	11,8	49	22,9	224	12,3	51	22,8	1,01		Algorithm converged.	0,64	1,57	0,001		Algorithm converged.	-0,077	0,080		1,006		Algorithm converged.	0,713	1,419	0,9743	0,2486	0,994		Algorithm converged.	0,705	1,403
		Western Europe	665	36,7	174	26,2	677	37,1	162	23,9	1,13		Algorithm converged.	0,88	1,44	0,022		Algorithm converged.	-0,024	0,069		1,093		Algorithm converged.	0,908	1,316	0,3447		0,915		Algorithm converged.	0,760	1,101
		Asia Pacific	461	25,5	122	26,5	488	26,8	104	21,3	1,33		Algorithm converged.	0,98	1,79	0,052		Algorithm converged.	-0,003	0,106		1,242		Algorithm converged.	0,988	1,561	0,0633		0,805		Algorithm converged.	0,641	1,012
		Latin America	38	2,1	6	15,8	42	2,3	7	16,7	0,94		Algorithm converged.	0,28	3,09	-0,009		Algorithm converged.	-0,170	0,153		0,947		Algorithm converged.	0,349	2,571	0,9155		1,056		Algorithm converged.	0,389	2,864
		Other	162	8,9	32	19,8	163	8,9	44	27,0	0,67		Algorithm converged.	0,40	1,12	-0,072		Algorithm converged.	-0,164	0,019		0,732		Algorithm converged.	0,490	1,092	0,1260		1,367		Algorithm converged.	0,916	2,039
	Protocol version	Protocol A	1050	58,0	252	24,0	1090	59,8	246	22,6	1,08		Algorithm converged.	0,89	1,32	0,014		Algorithm converged.	-0,022	0,050		1,063		Algorithm converged.	0,912	1,240	0,4335	0,7776	0,940		Algorithm converged.	0,806	1,097
		Protocol amendment B	490	27,1	131	26,7	504	27,6	122	24,2	1,14		Algorithm converged.	0,86	1,52	0,025		Algorithm converged.	-0,029	0,079		1,104		Algorithm converged.	0,893	1,367	0,3605		0,905		Algorithm converged.	0,732	1,120
	Nodal status	0 positive nodes	266	14,7	58	21,8	281	15,4	62	22,1	0,98		Algorithm converged.	0,66	1,48	-0,003		Algorithm converged.	-0,072	0,067		0,988		Algorithm converged.	0,720	1,356	0,9416	0,5604	1,012		Algorithm converged.	0,737	1,388
		>= 1 positive nodes	1274	70,3	325	25,5	1313	72,0	306	23,3	1,13		Algorithm converged.	0,94	1,35	0,022		Algorithm converged.	-0,011	0,055		1,095		Algorithm converged.	0,956	1,254	0,1919		0,914		Algorithm converged.	0,798	1,046
	Menopausal status at randomization	Premenopausal	753	41,6	173	23,0	797	43,7	173	21,7	1,08		Algorithm converged.	0,85	1,37	0,013		Algorithm converged.	-0,029	0,054		1,058		Algorithm converged.	0,879	1,274	0,5489	0,8139	0,945		Algorithm converged.	0,785	1,138
		Postmenopausal	783	43,2	210	26,8	789	43,3	194	24,6	1,12		Algorithm converged.	0,90	1,41	0,022		Algorithm converged.	-0,021	0,066		1,091		Algorithm converged.	0,922	1,291	0,3116		0,917		Algorithm converged.	0,775	1,085

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	8	0,4	1	12,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1359	75,0	330	24,3	1419	77,8	326	23,0	1,08		Algorithm converged.	0,90	1,28	0,013		Algorithm converged.	-0,019	0,045	1,057		Algorithm converged.	0,925	1,208	0,4169	0,4486	0,946		Algorithm converged.	0,828	1,082
		>= 65	181	10,0	53	29,3	175	9,6	42	24,0	1,31		Algorithm converged.	0,82	2,10	0,053		Algorithm converged.	-0,039	0,144	1,220		Algorithm converged.	0,862	1,727	0,2619		0,820		Algorithm converged.	0,579	1,160
	Histological grade	Grade 1	27	1,5	6	22,2	22	1,2	7	31,8	0,61		Algorithm converged.	0,17	2,19	-0,096		Algorithm converged.	-0,346	0,154	0,698		Algorithm converged.	0,274	1,777	0,4513	0,1081	1,432		Algorithm converged.	0,563	3,643
		Grade 2	473	26,1	102	21,6	486	26,7	116	23,9	0,88		Algorithm converged.	0,65	1,19	-0,023		Algorithm converged.	-0,076	0,030	0,903		Algorithm converged.	0,715	1,142	0,3952		1,107		Algorithm converged.	0,876	1,399
		Grade 3	981	54,2	258	26,3	1027	56,3	228	22,2	1,25		Algorithm converged.	1,02	1,53	0,041		Algorithm converged.	0,004	0,078	1,185		Algorithm converged.	1,014	1,384	0,0324		0,844		Algorithm converged.	0,723	0,986
		Unevaluable/Unknown/Missing	59	3,3	17	28,8	59	3,2	17	28,8	1,00		Algorithm converged.	0,45	2,22	0,000		Algorithm converged.	-0,163	0,163	1,000		Algorithm converged.	0,567	1,763	1,0000		1,000		Algorithm converged.	0,567	1,763
	Type of surgery for primary tumor	Breast conserving surgery	609	33,6	174	28,6	599	32,9	150	25,0	1,20		Algorithm converged.	0,93	1,55	0,035		Algorithm converged.	-0,015	0,085	1,141		Algorithm converged.	0,946	1,376	0,1669	0,4169	0,876		Algorithm converged.	0,727	1,057
		Mastectomy	931	51,4	209	22,4	994	54,5	217	21,8	1,04		Algorithm converged.	0,84	1,29	0,006		Algorithm converged.	-0,031	0,043	1,028		Algorithm converged.	0,870	1,216	0,7441		0,972		Algorithm converged.	0,822	1,150
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	567	31,3	145	25,6	580	31,8	144	24,8	1,04		Algorithm converged.	0,80	1,36	0,007		Algorithm converged.	-0,043	0,058	1,030		Algorithm converged.	0,844	1,257	0,7712	0,4750	0,971		Algorithm converged.	0,795	1,185

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	848	46,8	205	24,2	862	47,3	196	22,7	1,08		Algorithm converged.	0,87	1,36	0,014		Algorithm converged.	-0,026	0,055	1,063		Algorithm converged.	0,896	1,262	0,4833		0,941		Algorithm converged.	0,792	1,116
		>= 5 cm	123	6,8	32	26,0	150	8,2	28	18,7	1,53		Algorithm converged.	0,86	2,72	0,073		Algorithm converged.	-0,026	0,173	1,394		Algorithm converged.	0,891	2,181	0,1461		0,718		Algorithm converged.	0,459	1,123
		Missing	2	0,1	1	50,0	2	0,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Loco-regional radiotherapy	Yes	1191	65,8	308	25,9	1205	66,1	281	23,3	1,15		Algorithm converged.	0,95	1,38	0,025		Algorithm converged.	-0,009	0,060	1,109		Algorithm converged.	0,964	1,276	0,1490	0,3594	0,902		Algorithm converged.	0,784	1,038
		No	349	19,3	75	21,5	389	21,3	87	22,4	0,95		Algorithm converged.	0,67	1,35	-0,009		Algorithm converged.	-0,069	0,051	0,961		Algorithm converged.	0,731	1,262	0,7744		1,041		Algorithm converged.	0,792	1,367
	Race	White	1019	56,3	247	24,2	1059	58,1	246	23,2	1,06		Algorithm converged.	0,86	1,29	0,010		Algorithm converged.	-0,026	0,047	1,043		Algorithm converged.	0,894	1,217	0,5885	0,4244	0,958		Algorithm converged.	0,821	1,118
		Black	21	1,2	4	19,0	27	1,5	8	29,6	0,56		Algorithm converged.	0,14	2,19	-0,106		Algorithm converged.	-0,346	0,135	0,643		Algorithm converged.	0,224	1,848	0,4122		1,556		Algorithm converged.	0,541	4,472
		Asian	450	24,8	124	27,6	460	25,2	104	22,6	1,30		Algorithm converged.	0,96	1,76	0,049		Algorithm converged.	-0,007	0,106	1,219		Algorithm converged.	0,972	1,528	0,0860		0,820		Algorithm converged.	0,655	1,028
		Other	47	2,6	8	17,0	47	2,6	10	21,3	0,76		Algorithm converged.	0,27	2,13	-0,043		Algorithm converged.	-0,201	0,116	0,800		Algorithm converged.	0,346	1,848	0,6014		1,250		Algorithm converged.	0,541	2,887
		Missing	3	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1362	75,2	216	15,9	1327	72,8	243	18,3	0,84		Algorithm converged.	0,69	1,03	-0,025		Algorithm converged.	-0,053	0,004	0,866		Algorithm converged.	0,733	1,023	0,0914		1,155		Algorithm converged.	0,977	1,364

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	6	13,6	35	1,9	6	17,1	0,76		Algorithm converged.	0,22	2,61	-0,035		Algorithm converged.	-0,196	0,126	0,795		Algorithm converged.	0,281	2,252	0,6665	0,7493	1,257		Algorithm converged.	0,444	3,560
		0 positive nodes, tumor > 1 cm	212	11,7	29	13,7	222	12,2	35	15,8	0,85		Algorithm converged.	0,50	1,44	-0,021		Algorithm converged.	-0,087	0,046	0,868		Algorithm converged.	0,551	1,367	0,5406		1,153		Algorithm converged.	0,731	1,816
		1-3 positive nodes	694	38,3	119	17,1	656	36,0	120	18,3	0,92		Algorithm converged.	0,70	1,22	-0,011		Algorithm converged.	-0,052	0,029	0,937		Algorithm converged.	0,745	1,180	0,5815		1,067		Algorithm converged.	0,848	1,343
		>= 4 positive nodes	412	22,7	62	15,0	414	22,7	82	19,8	0,72		Algorithm converged.	0,50	1,03	-0,048		Algorithm converged.	-0,099	0,004	0,760		Algorithm converged.	0,563	1,026	0,0730		1,316		Algorithm converged.	0,975	1,777
	Adjuvant chemotherapy regimen	Anthracycline	1087	60,0	183	16,8	1066	58,5	198	18,6	0,89		Algorithm converged.	0,71	1,11	-0,017		Algorithm converged.	-0,050	0,015	0,906		Algorithm converged.	0,755	1,088	0,2908	0,2520	1,103		Algorithm converged.	0,919	1,324
		Non-anthracycline	275	15,2	33	12,0	261	14,3	45	17,2	0,65		Algorithm converged.	0,40	1,06	-0,052		Algorithm converged.	-0,112	0,007	0,696		Algorithm converged.	0,459	1,055	0,0878		1,437		Algorithm converged.	0,948	2,178
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	664	36,7	106	16,0	644	35,3	107	16,6	0,95		Algorithm converged.	0,71	1,28	-0,007		Algorithm converged.	-0,047	0,034	0,961		Algorithm converged.	0,751	1,228	0,7499	0,2567	1,041		Algorithm converged.	0,814	1,331
		Positive (ER and/or PgR positive)	698	38,5	110	15,8	683	37,5	136	19,9	0,75		Algorithm converged.	0,57	0,99	-0,042		Algorithm converged.	-0,082	-0,001	0,791		Algorithm converged.	0,630	0,994	0,0445		1,264		Algorithm converged.	1,006	1,587
	Geographical region II	USA/Canada	178	9,8	29	16,3	155	8,5	18	11,6	1,48		Algorithm converged.	0,79	2,79	0,047		Algorithm converged.	-0,027	0,121	1,403		Algorithm converged.	0,812	2,425	0,2253	-	0,713		Algorithm converged.	0,412	1,232
		Western Europe	588	32,5	104	17,7	577	31,7	125	21,7	0,78		Algorithm converged.	0,58	1,04	-0,040		Algorithm converged.	-0,085	0,006	0,816		Algorithm converged.	0,646	1,031	0,0886		1,225		Algorithm converged.	0,970	1,547
		Asia Pacific	415	22,9	66	15,9	428	23,5	67	15,7	1,02		Algorithm converged.	0,70	1,48	0,002		Algorithm converged.	-0,047	0,052	1,016		Algorithm converged.	0,744	1,388	0,9209		0,984		Algorithm converged.	0,721	1,345
		Latin America	34	1,9	1	2,9	36	2,0	7	19,4	0,13		Algorithm converged.	0,01	1,08	-0,165		Algorithm converged.	-0,306	-0,024	0,151		Algorithm converged.	0,020	1,166	0,0699		6,611		Algorithm converged.	0,858	50,955

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	147	8,1	16	10,9	131	7,2	26	19,8	0,49		Algorithm converged.	0,25	0,97	-0,090		Algorithm converged.	-0,174	-0,005	0,548		Algorithm converged.	0,308	0,976	0,0411		1,823		Algorithm converged.	1,025	3,246
	Protocol version	Protocol A	957	52,8	141	14,7	917	50,3	169	18,4	0,76		Algorithm converged.	0,60	0,98	-0,037		Algorithm converged.	-0,071	-0,003	0,799		Algorithm converged.	0,652	0,981	0,0318	0,1684	1,251		Algorithm converged.	1,020	1,535
		Protocol amendment B	405	22,4	75	18,5	410	22,5	74	18,0	1,03		Algorithm converged.	0,72	1,47	0,005		Algorithm converged.	-0,048	0,058	1,026		Algorithm converged.	0,768	1,372	0,8623		0,975		Algorithm converged.	0,729	1,303
	Nodal status	0 positive nodes	256	14,1	35	13,7	257	14,1	41	16,0	0,83		Algorithm converged.	0,51	1,36	-0,023		Algorithm converged.	-0,084	0,039	0,857		Algorithm converged.	0,565	1,300	0,4677	0,9606	1,167		Algorithm converged.	0,769	1,770
		>= 1 positive nodes	1106	61,1	181	16,4	1070	58,7	202	18,9	0,84		Algorithm converged.	0,67	1,05	-0,025		Algorithm converged.	-0,057	0,007	0,867		Algorithm converged.	0,723	1,040	0,1242		1,154		Algorithm converged.	0,961	1,384
	Menopausal status at randomization	Premenopausal	663	36,6	92	13,9	660	36,2	116	17,6	0,76		Algorithm converged.	0,56	1,02	-0,037		Algorithm converged.	-0,076	0,002	0,790		Algorithm converged.	0,614	1,015	0,0655	0,2790	1,267		Algorithm converged.	0,985	1,629
		Postmenopausal	695	38,4	124	17,8	661	36,3	124	18,8	0,94		Algorithm converged.	0,71	1,24	-0,009		Algorithm converged.	-0,050	0,032	0,951		Algorithm converged.	0,759	1,191	0,6622		1,051		Algorithm converged.	0,840	1,317
		Unknown/Missing	4	0,2	0	0,0	6	0,3	3	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Age II	< 65	1209	66,8	173	14,3	1185	65,0	212	17,9	0,77		Algorithm converged.	0,62	0,95	-0,036		Algorithm converged.	-0,065	-0,006	0,800		Algorithm converged.	0,665	0,962	0,0174	0,0330	1,250		Algorithm converged.	1,040	1,503
		>= 65	153	8,4	43	28,1	142	7,8	31	21,8	1,40		Algorithm converged.	0,82	2,38	0,063		Algorithm converged.	-0,036	0,161	1,287		Algorithm converged.	0,862	1,923	0,2174		0,777		Algorithm converged.	0,520	1,160

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	26	1,4	6	23,1	20	1,1	4	20,0	1,20		Algorithm converged.	0,29	4,99	0,031		Algorithm converged.	-0,208	0,269	1,154		Algorithm converged.	0,375	3,546	0,8028	0,7803	0,867		Algorithm converged.	0,282	2,664
		Grade 2	428	23,6	58	13,6	407	22,3	67	16,5	0,80		Algorithm converged.	0,54	1,16	-0,029		Algorithm converged.	-0,078	0,019	0,823		Algorithm converged.	0,595	1,139	0,2396		1,215		Algorithm converged.	0,878	1,680
		Grade 3	859	47,4	147	17,1	849	46,6	159	18,7	0,90		Algorithm converged.	0,70	1,15	-0,016		Algorithm converged.	-0,053	0,020	0,914		Algorithm converged.	0,746	1,120	0,3844		1,094		Algorithm converged.	0,893	1,341
		Unevaluable/Unknown/Missing	49	2,7	5	10,2	51	2,8	13	25,5	0,33		Algorithm converged.	0,11	1,02	-0,153		Algorithm converged.	-0,299	-0,006	0,400		Algorithm converged.	0,154	1,039	0,0600		2,498		Algorithm converged.	0,962	6,485
	Type of surgery for primary tumor	Breast conserving surgery	547	30,2	91	16,6	519	28,5	98	18,9	0,86		Algorithm converged.	0,63	1,17	-0,022		Algorithm converged.	-0,068	0,023	0,881		Algorithm converged.	0,680	1,141	0,3375	0,8604	1,135		Algorithm converged.	0,876	1,470
		Mastectomy	815	45,0	125	15,3	808	44,3	145	17,9	0,83		Algorithm converged.	0,64	1,08	-0,026		Algorithm converged.	-0,062	0,010	0,855		Algorithm converged.	0,687	1,063	0,1590		1,170		Algorithm converged.	0,940	1,456
	Tumor size	0 - < 2 cm	515	28,4	78	15,1	490	26,9	84	17,1	0,86		Algorithm converged.	0,62	1,21	-0,020		Algorithm converged.	-0,065	0,026	0,883		Algorithm converged.	0,666	1,172	0,3898	0,5209	1,132		Algorithm converged.	0,853	1,501
		>= 2 - < 5 cm	745	41,1	125	16,8	721	39,6	135	18,7	0,88		Algorithm converged.	0,67	1,14	-0,019		Algorithm converged.	-0,059	0,020	0,896		Algorithm converged.	0,719	1,117	0,3299		1,116		Algorithm converged.	0,895	1,392
		>= 5 cm	100	5,5	13	13,0	114	6,3	24	21,1	0,56		Algorithm converged.	0,27	1,17	-0,081		Algorithm converged.	-0,180	0,019	0,618		Algorithm converged.	0,332	1,147	0,1270		1,619		Algorithm converged.	0,872	3,008
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1042	57,5	170	16,3	1012	55,5	189	18,7	0,85		Algorithm converged.	0,68	1,07	-0,024		Algorithm converged.	-0,056	0,009	0,874		Algorithm converged.	0,724	1,055	0,1594	0,8438	1,145		Algorithm converged.	0,948	1,382
		No	320	17,7	46	14,4	315	17,3	54	17,1	0,81		Algorithm converged.	0,53	1,25	-0,028		Algorithm converged.	-0,084	0,029	0,839		Algorithm converged.	0,584	1,203	0,3393		1,193		Algorithm converged.	0,831	1,711
	Race	White	896	49,5	146	16,3	879	48,2	171	19,5	0,81		Algorithm converged.	0,63	1,03	-0,032		Algorithm converged.	-0,067	0,004	0,838		Algorithm converged.	0,686	1,023	0,0829	-	1,194		Algorithm converged.	0,977	1,459
		Black	18	1,0	2	11,1	19	1,0	3	15,8	0,67		Algorithm converged.	0,10	4,54	-0,047		Algorithm converged.	-0,266	0,172	0,704		Algorithm converged.	0,133	3,735	0,6799		1,421		Algorithm converged.	0,268	7,541

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asian	400	22,1	63	15,8	395	21,7	62	15,7	1,00		Algorithm converged.	0,69	1,47	0,001		Algorithm converged.	-0,050	0,051	1,003		Algorithm converged.	0,727	1,384	0,9834		0,997		Algorithm converged.	0,722	1,375
		Other	44	2,4	4	9,1	33	1,8	7	21,2	0,37		Algorithm converged.	0,10	1,40	-0,121		Algorithm converged.	-0,285	0,042	0,429		Algorithm converged.	0,137	1,343	0,1461		2,333		Algorithm converged.	0,744	7,314
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC02_W15_SG.xls
26OCT2020 15:37

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Emotional Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	200	13,0	1593	87,4	230	14,4	0,89		Algorithm converged.	0,72	1,09	-0,014		Algorithm converged.	-0,038	0,010	0,902		Algorithm converged.	0,757	1,076	0,2530		1,108		Algorithm converged.	0,929	1,321
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	8	18,6	35	1,9	6	17,1	1,10		Algorithm converged.	0,34	3,55	0,015		Algorithm converged.	-0,156	0,185	1,085		Algorithm converged.	0,416	2,834	0,8673	0,7603	0,921		Algorithm converged.	0,353	2,406
		0 positive nodes, tumor > 1 cm	225	12,4	34	15,1	248	13,6	41	16,5	0,90		Algorithm converged.	0,55	1,47	-0,014		Algorithm converged.	-0,080	0,052	0,914		Algorithm converged.	0,602	1,387	0,6729		1,094		Algorithm converged.	0,721	1,661
		1-3 positive nodes	766	42,3	95	12,4	793	43,5	101	12,7	0,97		Algorithm converged.	0,72	1,31	-0,003		Algorithm converged.	-0,036	0,030	0,974		Algorithm converged.	0,749	1,265	0,8422		1,027		Algorithm converged.	0,790	1,334
		>= 4 positive nodes	501	27,7	63	12,6	517	28,4	82	15,9	0,76		Algorithm converged.	0,54	1,09	-0,033		Algorithm converged.	-0,076	0,010	0,793		Algorithm converged.	0,585	1,075	0,1351		1,261		Algorithm converged.	0,930	1,710
	Adjuvant chemotherapy regimen	Anthracycline	1228	67,8	159	12,9	1276	70,0	197	15,4	0,81		Algorithm converged.	0,65	1,02	-0,025		Algorithm converged.	-0,052	0,002	0,839		Algorithm converged.	0,691	1,018	0,0750	0,0765	1,192		Algorithm converged.	0,982	1,447
		Non-anthracycline	307	17,0	41	13,4	317	17,4	33	10,4	1,33		Algorithm converged.	0,81	2,16	0,029		Algorithm converged.	-0,021	0,080	1,283		Algorithm converged.	0,834	1,973	0,2569		0,779		Algorithm converged.	0,507	1,199
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	749	41,4	96	12,8	752	41,3	112	14,9	0,84		Algorithm converged.	0,63	1,13	-0,021		Algorithm converged.	-0,056	0,014	0,861		Algorithm converged.	0,668	1,108	0,2450	0,6107	1,162		Algorithm converged.	0,902	1,497
		Positive (ER and/or PgR positive)	786	43,4	104	13,2	841	46,1	118	14,0	0,93		Algorithm converged.	0,70	1,24	-0,008		Algorithm converged.	-0,041	0,025	0,943		Algorithm converged.	0,738	1,205	0,6389		1,060		Algorithm converged.	0,830	1,355

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	30	14,1	224	12,3	24	10,7	1,37		Algorithm converged.	0,77	2,42	0,034		Algorithm converged.	-0,028	0,096	1,315		Algorithm converged.	0,795	2,174	0,2865	-	0,761		Algorithm converged.	0,460	1,258
		Western Europe	661	36,5	96	14,5	677	37,1	115	17,0	0,83		Algorithm converged.	0,62	1,12	-0,025		Algorithm converged.	-0,064	0,014	0,855		Algorithm converged.	0,667	1,097	0,2173		1,170		Algorithm converged.	0,912	1,500
		Asia Pacific	461	25,5	48	10,4	487	26,7	62	12,7	0,80		Algorithm converged.	0,53	1,19	-0,023		Algorithm converged.	-0,064	0,017	0,818		Algorithm converged.	0,574	1,166	0,2665		1,223		Algorithm converged.	0,858	1,743
		Latin America	38	2,1	4	10,5	42	2,3	4	9,5	1,12		Algorithm converged.	0,26	4,82	0,010		Algorithm converged.	-0,122	0,142	1,105		Algorithm converged.	0,297	4,115	0,8814		0,905		Algorithm converged.	0,243	3,369
		Other	162	8,9	22	13,6	163	8,9	25	15,3	0,87		Algorithm converged.	0,47	1,61	-0,018		Algorithm converged.	-0,094	0,059	0,885		Algorithm converged.	0,521	1,504	0,6528		1,129		Algorithm converged.	0,665	1,919
	Protocol version	Protocol A	1048	57,9	136	13,0	1089	59,7	161	14,8	0,86		Algorithm converged.	0,67	1,10	-0,018		Algorithm converged.	-0,047	0,011	0,878		Algorithm converged.	0,710	1,085	0,2279	0,6454	1,139		Algorithm converged.	0,922	1,408
		Protocol amendment B	487	26,9	64	13,1	504	27,6	69	13,7	0,95		Algorithm converged.	0,66	1,37	-0,005		Algorithm converged.	-0,048	0,037	0,960		Algorithm converged.	0,699	1,317	0,8000		1,042		Algorithm converged.	0,759	1,430
	Nodal status	0 positive nodes	268	14,8	42	15,7	283	15,5	47	16,6	0,93		Algorithm converged.	0,59	1,47	-0,009		Algorithm converged.	-0,071	0,052	0,944		Algorithm converged.	0,645	1,381	0,7655	0,8002	1,060		Algorithm converged.	0,724	1,551
		>= 1 positive nodes	1267	70,0	158	12,5	1310	71,9	183	14,0	0,88		Algorithm converged.	0,70	1,10	-0,015		Algorithm converged.	-0,041	0,011	0,893		Algorithm converged.	0,732	1,089	0,2620		1,120		Algorithm converged.	0,919	1,366
	Menopausal status at randomization	Premenopausal	749	41,4	99	13,2	796	43,7	124	15,6	0,83		Algorithm converged.	0,62	1,10	-0,024		Algorithm converged.	-0,059	0,011	0,848		Algorithm converged.	0,664	1,084	0,1880	0,4555	1,179		Algorithm converged.	0,923	1,505
		Postmenopausal	782	43,2	101	12,9	789	43,3	105	13,3	0,97		Algorithm converged.	0,72	1,30	-0,004		Algorithm converged.	-0,037	0,029	0,971		Algorithm converged.	0,752	1,252	0,8178		1,030		Algorithm converged.	0,799	1,329

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	8	0,4	1	12,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1355	74,8	174	12,8	1418	77,8	215	15,2	0,82		Algorithm converged.	0,66	1,02	-0,023		Algorithm converged.	-0,049	0,003		0,847		Algorithm converged.	0,704	1,020	0,0792	0,0282	1,181		Algorithm converged.	0,981	1,421
		>= 65	180	9,9	26	14,4	175	9,6	15	8,6	1,80		Algorithm converged.	0,92	3,53	0,059		Algorithm converged.	-0,007	0,125		1,685		Algorithm converged.	0,924	3,072	0,0885		0,593		Algorithm converged.	0,326	1,082
	Histological grade	Grade 1	27	1,5	5	18,5	22	1,2	4	18,2	1,02		Algorithm converged.	0,24	4,38	0,003		Algorithm converged.	-0,214	0,221		1,019		Algorithm converged.	0,310	3,342	0,9759	-	0,982		Algorithm converged.	0,299	3,221
		Grade 2	472	26,1	58	12,3	486	26,7	62	12,8	0,96		Algorithm converged.	0,65	1,40	-0,005		Algorithm converged.	-0,047	0,037		0,963		Algorithm converged.	0,689	1,346	0,8265		1,038		Algorithm converged.	0,743	1,451
		Grade 3	977	53,9	131	13,4	1026	56,3	157	15,3	0,86		Algorithm converged.	0,67	1,10	-0,019		Algorithm converged.	-0,050	0,012		0,876		Algorithm converged.	0,707	1,086	0,2279		1,141		Algorithm converged.	0,921	1,415
		Unevaluable/Unknown/Missing	59	3,3	6	10,2	59	3,2	7	11,9	0,84		Algorithm converged.	0,26	2,67	-0,017		Algorithm converged.	-0,130	0,096		0,857		Algorithm converged.	0,306	2,398	0,7690		1,167		Algorithm converged.	0,417	3,265
	Type of surgery for primary tumor	Breast conserving surgery	605	33,4	78	12,9	601	33,0	90	15,0	0,84		Algorithm converged.	0,61	1,17	-0,021		Algorithm converged.	-0,060	0,018		0,861		Algorithm converged.	0,650	1,141	0,2970	0,6810	1,162		Algorithm converged.	0,877	1,539
		Mastectomy	930	51,4	122	13,1	991	54,4	140	14,1	0,92		Algorithm converged.	0,71	1,19	-0,010		Algorithm converged.	-0,041	0,021		0,929		Algorithm converged.	0,741	1,164	0,5199		1,077		Algorithm converged.	0,859	1,350
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	564	31,1	77	13,7	581	31,9	70	12,0	1,15		Algorithm converged.	0,82	1,63	0,016		Algorithm converged.	-0,023	0,055		1,133		Algorithm converged.	0,838	1,533	0,4176	0,1627	0,882		Algorithm converged.	0,652	1,194

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	846	46,7	103	12,2	861	47,2	134	15,6	0,75		Algorithm converged.	0,57	0,99	-0,034		Algorithm converged.	-0,067	-0,001	0,782		Algorithm converged.	0,616	0,993	0,0438		1,278		Algorithm converged.	1,007	1,623
		>= 5 cm	123	6,8	20	16,3	149	8,2	25	16,8	0,96		Algorithm converged.	0,51	1,83	-0,005		Algorithm converged.	-0,094	0,083	0,969		Algorithm converged.	0,566	1,659	0,9089		1,032		Algorithm converged.	0,603	1,766
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1186	65,5	162	13,7	1204	66,0	185	15,4	0,87		Algorithm converged.	0,69	1,09	-0,017		Algorithm converged.	-0,045	0,011	0,889		Algorithm converged.	0,731	1,080	0,2370	0,8042	1,125		Algorithm converged.	0,926	1,367
		No	349	19,3	38	10,9	389	21,3	45	11,6	0,93		Algorithm converged.	0,59	1,48	-0,007		Algorithm converged.	-0,052	0,039	0,941		Algorithm converged.	0,627	1,414	0,7705		1,062		Algorithm converged.	0,707	1,596
	Race	White	1014	56,0	145	14,3	1059	58,1	167	15,8	0,89		Algorithm converged.	0,70	1,13	-0,015		Algorithm converged.	-0,045	0,016	0,907		Algorithm converged.	0,739	1,113	0,3499	-	1,103		Algorithm converged.	0,898	1,354
		Black	21	1,2	2	9,5	27	1,5	4	14,8	0,61		Algorithm converged.	0,10	3,67	-0,053		Algorithm converged.	-0,237	0,131	0,643		Algorithm converged.	0,130	3,180	0,5880		1,556		Algorithm converged.	0,314	7,695
		Asian	449	24,8	47	10,5	459	25,2	55	12,0	0,86		Algorithm converged.	0,57	1,30	-0,015		Algorithm converged.	-0,056	0,026	0,874		Algorithm converged.	0,605	1,261	0,4704		1,145		Algorithm converged.	0,793	1,652
		Other	47	2,6	6	12,8	47	2,6	4	8,5	1,57		Algorithm converged.	0,41	5,98	0,043		Algorithm converged.	-0,082	0,167	1,500		Algorithm converged.	0,452	4,974	0,5074		0,667		Algorithm converged.	0,201	2,211
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1359	75,0	162	11,9	1324	72,6	177	13,4	0,88		Algorithm converged.	0,70	1,10	-0,014		Algorithm converged.	-0,040	0,011	0,892		Algorithm converged.	0,731	1,088	0,2594		1,121		Algorithm converged.	0,919	1,369

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	4	9,1	35	1,9	3	8,6	1,07		Algorithm converged.	0,22	5,11	0,005		Algorithm converged.	-0,121	0,131	1,061		Algorithm converged.	0,254	4,430	0,9357	-	0,943		Algorithm converged.	0,226	3,938
		0 positive nodes, tumor > 1 cm	213	11,8	16	7,5	222	12,2	33	14,9	0,47		Algorithm converged.	0,25	0,87	-0,074		Algorithm converged.	-0,132	-0,015	0,505		Algorithm converged.	0,287	0,891	0,0182		1,979		Algorithm converged.	1,123	3,488
		1-3 positive nodes	691	38,2	84	12,2	655	35,9	85	13,0	0,93		Algorithm converged.	0,67	1,28	-0,008		Algorithm converged.	-0,044	0,027	0,937		Algorithm converged.	0,707	1,242	0,6497		1,068		Algorithm converged.	0,805	1,415
		>= 4 positive nodes	411	22,7	58	14,1	412	22,6	56	13,6	1,04		Algorithm converged.	0,70	1,55	0,005		Algorithm converged.	-0,042	0,052	1,038		Algorithm converged.	0,738	1,460	0,8292		0,963		Algorithm converged.	0,685	1,354
	Adjuvant chemotherapy regimen	Anthracycline	1084	59,9	130	12,0	1063	58,3	150	14,1	0,83		Algorithm converged.	0,64	1,07	-0,021		Algorithm converged.	-0,050	0,007	0,850		Algorithm converged.	0,683	1,058	0,1456	0,2995	1,177		Algorithm converged.	0,945	1,465
		Non-anthracycline	275	15,2	32	11,6	261	14,3	27	10,3	1,14		Algorithm converged.	0,66	1,96	0,013		Algorithm converged.	-0,040	0,066	1,125		Algorithm converged.	0,694	1,824	0,6333		0,889		Algorithm converged.	0,548	1,442
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	663	36,6	67	10,1	643	35,3	84	13,1	0,75		Algorithm converged.	0,53	1,05	-0,030		Algorithm converged.	-0,064	0,005	0,774		Algorithm converged.	0,572	1,046	0,0958	0,2112	1,293		Algorithm converged.	0,956	1,749
		Positive (ER and/or PgR positive)	696	38,4	95	13,6	681	37,4	93	13,7	1,00		Algorithm converged.	0,73	1,36	0,000		Algorithm converged.	-0,036	0,036	0,999		Algorithm converged.	0,766	1,304	0,9970		1,001		Algorithm converged.	0,767	1,305
	Geographical region II	USA/Canada	178	9,8	30	16,9	155	8,5	14	9,0	2,04		Algorithm converged.	1,04	4,01	0,078		Algorithm converged.	0,007	0,149	1,866		Algorithm converged.	1,027	3,389	0,0405	-	0,536		Algorithm converged.	0,295	0,973
		Western Europe	586	32,4	81	13,8	574	31,5	93	16,2	0,83		Algorithm converged.	0,60	1,15	-0,024		Algorithm converged.	-0,065	0,017	0,853		Algorithm converged.	0,648	1,123	0,2572		1,172		Algorithm converged.	0,891	1,543
		Asia Pacific	414	22,9	32	7,7	428	23,5	49	11,4	0,65		Algorithm converged.	0,41	1,03	-0,037		Algorithm converged.	-0,077	0,002	0,675		Algorithm converged.	0,442	1,032	0,0697		1,481		Algorithm converged.	0,969	2,264
		Latin America	34	1,9	1	2,9	36	2,0	1	2,8	1,06		Algorithm converged.	0,06	17,66	0,002		Algorithm converged.	-0,077	0,080	1,059		Algorithm converged.	0,069	16,266	0,9673		0,944		Algorithm converged.	0,061	14,508

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	147	8,1	18	12,2	131	7,2	20	15,3	0,77		Algorithm converged.	0,39	1,54	-0,030		Algorithm converged.	-0,111	0,051	0,802		Algorithm converged.	0,444	1,449	0,4649		1,247		Algorithm converged.	0,690	2,253
	Protocol version	Protocol A	955	52,7	108	11,3	915	50,2	125	13,7	0,81		Algorithm converged.	0,61	1,06	-0,024		Algorithm converged.	-0,054	0,006	0,828		Algorithm converged.	0,651	1,053	0,1243	0,2749	1,208		Algorithm converged.	0,949	1,537
		Protocol amendment B	404	22,3	54	13,4	409	22,4	52	12,7	1,06		Algorithm converged.	0,70	1,59	0,007		Algorithm converged.	-0,040	0,053	1,051		Algorithm converged.	0,737	1,500	0,7824		0,951		Algorithm converged.	0,667	1,357
	Nodal status	0 positive nodes	257	14,2	20	7,8	257	14,1	36	14,0	0,52		Algorithm converged.	0,29	0,92	-0,062		Algorithm converged.	-0,116	-0,009	0,556		Algorithm converged.	0,331	0,933	0,0263	0,0457	1,800		Algorithm converged.	1,072	3,023
		>= 1 positive nodes	1102	60,9	142	12,9	1067	58,5	141	13,2	0,97		Algorithm converged.	0,76	1,25	-0,003		Algorithm converged.	-0,032	0,025	0,975		Algorithm converged.	0,785	1,212	0,8201		1,026		Algorithm converged.	0,825	1,274
	Menopausal status at randomization	Premenopausal	660	36,4	90	13,6	659	36,1	95	14,4	0,94		Algorithm converged.	0,69	1,28	-0,008		Algorithm converged.	-0,045	0,030	0,946		Algorithm converged.	0,724	1,236	0,6836	0,6155	1,057		Algorithm converged.	0,809	1,381
		Postmenopausal	695	38,4	72	10,4	659	36,1	80	12,1	0,84		Algorithm converged.	0,60	1,17	-0,018		Algorithm converged.	-0,051	0,016	0,853		Algorithm converged.	0,632	1,152	0,3003		1,172		Algorithm converged.	0,868	1,582
		Unknown/Missing	4	0,2	0	0,0	6	0,3	2	33,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1206	66,6	148	12,3	1182	64,8	164	13,9	0,87		Algorithm converged.	0,68	1,10	-0,016		Algorithm converged.	-0,043	0,011	0,884		Algorithm converged.	0,719	1,088	0,2456	0,7489	1,131		Algorithm converged.	0,919	1,391
		>= 65	153	8,4	14	9,2	142	7,8	13	9,2	1,00		Algorithm converged.	0,45	2,21	0,000		Algorithm converged.	-0,066	0,066	0,999		Algorithm converged.	0,487	2,052	0,9989		1,001		Algorithm converged.	0,487	2,055

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	26	1,4	5	19,2	20	1,1	4	20,0	0,95		Algorithm converged.	0,22	4,13	-0,008		Algorithm converged.	-0,239	0,224	0,962		Algorithm converged.	0,296	3,124	0,9480	-	1,040		Algorithm converged.	0,320	3,379
		Grade 2	426	23,5	44	10,3	406	22,3	52	12,8	0,78		Algorithm converged.	0,51	1,20	-0,025		Algorithm converged.	-0,068	0,019	0,806		Algorithm converged.	0,553	1,177	0,2643		1,240		Algorithm converged.	0,850	1,809
		Grade 3	858	47,4	111	12,9	848	46,5	114	13,4	0,96		Algorithm converged.	0,72	1,27	-0,005		Algorithm converged.	-0,037	0,027	0,962		Algorithm converged.	0,754	1,228	0,7573		1,039		Algorithm converged.	0,815	1,326
		Unevaluable/Unknown/Missing	49	2,7	2	4,1	50	2,7	7	14,0	0,26		Algorithm converged.	0,05	1,33	-0,099		Algorithm converged.	-0,210	0,012	0,292		Algorithm converged.	0,064	1,335	0,1123		3,430		Algorithm converged.	0,749	15,703
	Type of surgery for primary tumor	Breast conserving surgery	545	30,1	54	9,9	517	28,4	63	12,2	0,79		Algorithm converged.	0,54	1,17	-0,023		Algorithm converged.	-0,061	0,015	0,813		Algorithm converged.	0,577	1,146	0,2371	0,5020	1,230		Algorithm converged.	0,873	1,733
		Mastectomy	814	44,9	108	13,3	807	44,3	114	14,1	0,93		Algorithm converged.	0,70	1,23	-0,009		Algorithm converged.	-0,042	0,025	0,939		Algorithm converged.	0,735	1,199	0,6152		1,065		Algorithm converged.	0,834	1,360
	Tumor size	0 - < 2 cm	514	28,4	57	11,1	490	26,9	63	12,9	0,85		Algorithm converged.	0,58	1,24	-0,018		Algorithm converged.	-0,058	0,023	0,863		Algorithm converged.	0,616	1,207	0,3886	0,5326	1,159		Algorithm converged.	0,828	1,623
		>= 2 - < 5 cm	743	41,0	90	12,1	719	39,4	101	14,0	0,84		Algorithm converged.	0,62	1,14	-0,019		Algorithm converged.	-0,054	0,015	0,862		Algorithm converged.	0,662	1,124	0,2731		1,160		Algorithm converged.	0,890	1,512
		>= 5 cm	100	5,5	15	15,0	113	6,2	13	11,5	1,36		Algorithm converged.	0,61	3,01	0,035		Algorithm converged.	-0,056	0,126	1,304		Algorithm converged.	0,653	2,605	0,4525		0,767		Algorithm converged.	0,384	1,533
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1039	57,4	129	12,4	1009	55,3	132	13,1	0,94		Algorithm converged.	0,73	1,22	-0,007		Algorithm converged.	-0,036	0,022	0,949		Algorithm converged.	0,757	1,191	0,6512	0,2603	1,054		Algorithm converged.	0,840	1,322
		No	320	17,7	33	10,3	315	17,3	45	14,3	0,69		Algorithm converged.	0,43	1,11	-0,040		Algorithm converged.	-0,091	0,011	0,722		Algorithm converged.	0,474	1,100	0,1296		1,385		Algorithm converged.	0,909	2,111
	Race	White	894	49,4	123	13,8	876	48,1	125	14,3	0,96		Algorithm converged.	0,73	1,25	-0,005		Algorithm converged.	-0,037	0,027	0,964		Algorithm converged.	0,765	1,215	0,7568	-	1,037		Algorithm converged.	0,823	1,306
		Black	18	1,0	3	16,7	19	1,0	4	21,1	0,75		Algorithm converged.	0,14	3,94	-0,044		Algorithm converged.	-0,295	0,208	0,792		Algorithm converged.	0,205	3,057	0,7347		1,263		Algorithm converged.	0,327	4,878

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asian	398	22,0	34	8,5	395	21,7	47	11,9	0,69		Algorithm converged.	0,43	1,10	-0,034		Algorithm converged.	-0,076	0,009	0,718		Algorithm converged.	0,472	1,091	0,1209		1,393		Algorithm converged.	0,916	2,117
		Other	44	2,4	2	4,5	33	1,8	1	3,0	1,52		Algorithm converged.	0,13	17,55	0,015		Algorithm converged.	-0,070	0,100	1,500		Algorithm converged.	0,142	15,849	0,7361		0,667		Algorithm converged.	0,063	7,044
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC03_W15_SG.xls
27OCT2020 9:51

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1536	84,8	607	39,5	1592	87,3	632	39,7	0,99		Algorithm converged.	0,86	1,15	-0,002		Algorithm converged.	-0,036	0,032	0,995		Algorithm converged.	0,913	1,085	0,9179		1,005		Algorithm converged.	0,921	1,095
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	17	39,5	35	1,9	7	20,0	2,62		Algorithm converged.	0,93	7,32	0,195		Algorithm converged.	-0,002	0,393	1,977		Algorithm converged.	0,926	4,221	0,0783	0,0573	0,506		Algorithm converged.	0,237	1,080
		0 positive nodes, tumor > 1 cm	225	12,4	82	36,4	248	13,6	112	45,2	0,70		Algorithm converged.	0,48	1,01	-0,087		Algorithm converged.	-0,175	0,001	0,807		Algorithm converged.	0,647	1,006	0,0565		1,239		Algorithm converged.	0,994	1,545
		1-3 positive nodes	767	42,4	307	40,0	792	43,4	313	39,5	1,02		Algorithm converged.	0,83	1,25	0,005		Algorithm converged.	-0,044	0,054	1,013		Algorithm converged.	0,896	1,144	0,8383		0,987		Algorithm converged.	0,874	1,116
		>= 4 positive nodes	501	27,7	201	40,1	517	28,4	200	38,7	1,06		Algorithm converged.	0,83	1,37	0,014		Algorithm converged.	-0,046	0,074	1,037		Algorithm converged.	0,891	1,208	0,6394		0,964		Algorithm converged.	0,828	1,123
	Adjuvant chemotherapy regimen	Anthracycline	1229	67,9	484	39,4	1276	70,0	509	39,9	0,98		Algorithm converged.	0,83	1,15	-0,005		Algorithm converged.	-0,043	0,033	0,987		Algorithm converged.	0,896	1,087	0,7947	0,7064	1,013		Algorithm converged.	0,920	1,116
		Non-anthracycline	307	17,0	123	40,1	316	17,3	123	38,9	1,05		Algorithm converged.	0,76	1,45	0,011		Algorithm converged.	-0,065	0,088	1,029		Algorithm converged.	0,847	1,250	0,7708		0,972		Algorithm converged.	0,800	1,180
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	749	41,4	301	40,2	752	41,3	307	40,8	0,97		Algorithm converged.	0,79	1,20	-0,006		Algorithm converged.	-0,056	0,043	0,984		Algorithm converged.	0,871	1,113	0,8014	0,8149	1,016		Algorithm converged.	0,899	1,148
		Positive (ER and/or PgR positive)	787	43,5	306	38,9	840	46,1	325	38,7	1,01		Algorithm converged.	0,83	1,23	0,002		Algorithm converged.	-0,045	0,049	1,005		Algorithm converged.	0,889	1,136	0,9369		0,995		Algorithm converged.	0,881	1,124

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	79	37,1	224	12,3	68	30,4	1,35		Algorithm converged.	0,91	2,01	0,067		Algorithm converged.	-0,021	0,156	1,222		Algorithm converged.	0,938	1,592	0,1377	0,0732	0,818		Algorithm converged.	0,628	1,066
		Western Europe	662	36,6	295	44,6	676	37,1	291	43,0	1,06		Algorithm converged.	0,86	1,32	0,015		Algorithm converged.	-0,038	0,068	1,035		Algorithm converged.	0,917	1,169	0,5766		0,966		Algorithm converged.	0,856	1,091
		Asia Pacific	461	25,5	177	38,4	487	26,7	197	40,5	0,92		Algorithm converged.	0,71	1,19	-0,021		Algorithm converged.	-0,083	0,042	0,949		Algorithm converged.	0,810	1,112	0,5175		1,054		Algorithm converged.	0,900	1,234
		Latin America	38	2,1	14	36,8	42	2,3	14	33,3	1,17		Algorithm converged.	0,47	2,93	0,035		Algorithm converged.	-0,174	0,244	1,105		Algorithm converged.	0,608	2,008	0,7424		0,905		Algorithm converged.	0,498	1,643
		Other	162	8,9	42	25,9	163	8,9	62	38,0	0,57		Algorithm converged.	0,36	0,91	-0,121		Algorithm converged.	-0,222	-0,021	0,682		Algorithm converged.	0,492	0,944	0,0211		1,467		Algorithm converged.	1,059	2,032
	Protocol version	Protocol A	1049	57,9	398	37,9	1088	59,7	427	39,2	0,95		Algorithm converged.	0,80	1,13	-0,013		Algorithm converged.	-0,054	0,028	0,967		Algorithm converged.	0,869	1,076	0,5356	0,3457	1,034		Algorithm converged.	0,929	1,151
		Protocol amendment B	487	26,9	209	42,9	504	27,6	205	40,7	1,10		Algorithm converged.	0,85	1,41	0,022		Algorithm converged.	-0,039	0,084	1,055		Algorithm converged.	0,911	1,222	0,4745		0,948		Algorithm converged.	0,818	1,098
	Nodal status	0 positive nodes	268	14,8	99	36,9	283	15,5	119	42,0	0,81		Algorithm converged.	0,57	1,14	-0,051		Algorithm converged.	-0,133	0,030	0,878		Algorithm converged.	0,714	1,081	0,2217	0,1925	1,138		Algorithm converged.	0,925	1,401
		>= 1 positive nodes	1268	70,0	508	40,1	1309	71,8	513	39,2	1,04		Algorithm converged.	0,89	1,21	0,009		Algorithm converged.	-0,029	0,047	1,022		Algorithm converged.	0,929	1,125	0,6506		0,978		Algorithm converged.	0,889	1,076
	Menopausal status at randomization	Premenopausal	750	41,4	310	41,3	795	43,6	325	40,9	1,02		Algorithm converged.	0,83	1,25	0,005		Algorithm converged.	-0,045	0,054	1,011		Algorithm converged.	0,897	1,139	0,8565	0,6343	0,989		Algorithm converged.	0,878	1,114
		Postmenopausal	782	43,2	294	37,6	789	43,3	306	38,8	0,95		Algorithm converged.	0,78	1,17	-0,012		Algorithm converged.	-0,060	0,036	0,969		Algorithm converged.	0,855	1,099	0,6282		1,032		Algorithm converged.	0,910	1,170
		Unknown/Missing	4	0,2	3	75,0	8	0,4	1	12,5	21,00		Algorithm converged.	0,96	458,84	0,625		Algorithm converged.	0,143	1,107	6,000		Algorithm converged.	0,881	40,872	0,0672		0,167		Algorithm converged.	0,024	1,135
	Age II	< 65	1356	74,9	538	39,7	1417	77,7	568	40,1	0,98		Algorithm converged.	0,84	1,14	-0,004		Algorithm converged.	-0,041	0,032	0,990		Algorithm converged.	0,903	1,085	0,8259	0,6925	1,010		Algorithm converged.	0,922	1,107
		>= 65	180	9,9	69	38,3	175	9,6	64	36,6	1,08		Algorithm converged.	0,70	1,66	0,018		Algorithm converged.	-0,083	0,118	1,048		Algorithm converged.	0,801	1,372	0,7318		0,954		Algorithm converged.	0,729	1,249

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	13	48,1	21	1,2	11	52,4	0,84		Algorithm converged.	0,27	2,64	-0,042		Algorithm converged.	-0,327	0,243	0,919		Algorithm converged.	0,522	1,618	0,7702	0,2055	1,088		Algorithm converged.	0,618	1,915
		Grade 2	472	26,1	190	40,3	486	26,7	171	35,2	1,24		Algorithm converged.	0,96	1,61	0,051		Algorithm converged.	-0,011	0,112	1,144		Algorithm converged.	0,972	1,347	0,1061		0,874		Algorithm converged.	0,742	1,029
		Grade 3	978	54,0	384	39,3	1026	56,3	419	40,8	0,94		Algorithm converged.	0,78	1,12	-0,016		Algorithm converged.	-0,059	0,027	0,961		Algorithm converged.	0,864	1,070	0,4724		1,040		Algorithm converged.	0,934	1,158
		Unevaluable/Unknown/Missing	59	3,3	20	33,9	59	3,2	31	52,5	0,46		Algorithm converged.	0,22	0,97	-0,186		Algorithm converged.	-0,362	-0,011	0,645		Algorithm converged.	0,419	0,993	0,0463		1,550		Algorithm converged.	1,007	2,385
	Type of surgery for primary tumor	Breast conserving surgery	606	33,5	223	36,8	600	32,9	248	41,3	0,83		Algorithm converged.	0,66	1,04	-0,045		Algorithm converged.	-0,100	0,010	0,890		Algorithm converged.	0,773	1,025	0,1071	0,0455	1,123		Algorithm converged.	0,975	1,294
		Mastectomy	930	51,4	384	41,3	991	54,4	383	38,6	1,12		Algorithm converged.	0,93	1,34	0,026		Algorithm converged.	-0,017	0,070	1,068		Algorithm converged.	0,957	1,192	0,2372		0,936		Algorithm converged.	0,839	1,044
		Missing	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	565	31,2	231	40,9	580	31,8	223	38,4	1,11		Algorithm converged.	0,87	1,40	0,024		Algorithm converged.	-0,032	0,081	1,063		Algorithm converged.	0,922	1,227	0,3995	0,3656	0,940		Algorithm converged.	0,815	1,085
		>= 2 - < 5 cm	846	46,7	323	38,2	861	47,2	349	40,5	0,91		Algorithm converged.	0,75	1,10	-0,024		Algorithm converged.	-0,070	0,023	0,942		Algorithm converged.	0,837	1,060	0,3198		1,062		Algorithm converged.	0,944	1,195
		>= 5 cm	123	6,8	52	42,3	149	8,2	58	38,9	1,15		Algorithm converged.	0,71	1,87	0,034		Algorithm converged.	-0,084	0,151	1,086		Algorithm converged.	0,814	1,449	0,5745		0,921		Algorithm converged.	0,690	1,228
		Missing	2	0,1	1	50,0	2	0,1	2	100,0	0,00		Algorithm converged.	0,00	0,00	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1187	65,5	478	40,3	1203	66,0	473	39,3	1,04		Algorithm converged.	0,88	1,23	0,010		Algorithm converged.	-0,030	0,049	1,024		Algorithm converged.	0,928	1,130	0,6348	0,2370	0,976		Algorithm converged.	0,885	1,078
		No	349	19,3	129	37,0	389	21,3	159	40,9	0,85		Algorithm converged.	0,63	1,14	-0,039		Algorithm converged.	-0,109	0,031	0,904		Algorithm converged.	0,754	1,085	0,2782		1,106		Algorithm converged.	0,922	1,326
	Race	White	1015	56,0	405	39,9	1058	58,0	424	40,1	0,99		Algorithm converged.	0,83	1,18	-0,002		Algorithm converged.	-0,044	0,040	0,996		Algorithm converged.	0,896	1,106	0,9355	0,5569	1,004		Algorithm converged.	0,904	1,116
		Black	21	1,2	8	38,1	27	1,5	9	33,3	1,23		Algorithm converged.	0,37	4,05	0,048		Algorithm converged.	-0,226	0,321	1,143		Algorithm converged.	0,533	2,451	0,7315		0,875		Algorithm converged.	0,408	1,876
		Asian	449	24,8	173	38,5	459	25,2	185	40,3	0,93		Algorithm converged.	0,71	1,21	-0,018		Algorithm converged.	-0,081	0,046	0,956		Algorithm converged.	0,813	1,123	0,5844		1,046		Algorithm converged.	0,890	1,229
		Other	47	2,6	20	42,6	47	2,6	14	29,8	1,75		Algorithm converged.	0,75	4,09	0,128		Algorithm converged.	-0,065	0,320	1,429		Algorithm converged.	0,824	2,477	0,2041		0,700		Algorithm converged.	0,404	1,214
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1360	75,1	490	36,0	1324	72,6	494	37,3	0,95		Algorithm converged.	0,81	1,11	-0,013		Algorithm converged.	-0,049	0,024	0,966		Algorithm converged.	0,874	1,067	0,4909		1,036		Algorithm converged.	0,938	1,144
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	16	36,4	35	1,9	7	20,0	2,29		Algorithm converged.	0,82	6,41	0,164		Algorithm converged.	-0,031	0,358	1,818		Algorithm converged.	0,842	3,924	0,1277	0,3554	0,550		Algorithm converged.	0,255	1,187
		0 positive nodes, tumor > 1 cm	213	11,8	72	33,8	222	12,2	83	37,4	0,86		Algorithm converged.	0,58	1,27	-0,036		Algorithm converged.	-0,126	0,054	0,904		Algorithm converged.	0,702	1,165	0,4359		1,106		Algorithm converged.	0,858	1,425

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	692	38,2	255	36,8	655	35,9	248	37,9	0,96		Algorithm converged.	0,77	1,19	-0,010		Algorithm converged.	-0,062	0,042	0,973		Algorithm converged.	0,848	1,118	0,7009		1,027		Algorithm converged.	0,895	1,180
		>= 4 positive nodes	411	22,7	147	35,8	412	22,6	156	37,9	0,91		Algorithm converged.	0,69	1,21	-0,021		Algorithm converged.	-0,087	0,045	0,945		Algorithm converged.	0,790	1,130	0,5329		1,059		Algorithm converged.	0,885	1,266
	Adjuvant chemotherapy regimen	Anthracycline	1085	59,9	388	35,8	1063	58,3	404	38,0	0,91		Algorithm converged.	0,76	1,08	-0,022		Algorithm converged.	-0,063	0,018	0,941		Algorithm converged.	0,842	1,051	0,2810	0,2989	1,063		Algorithm converged.	0,951	1,187
		Non-anthracycline	275	15,2	102	37,1	261	14,3	90	34,5	1,12		Algorithm converged.	0,79	1,60	0,026		Algorithm converged.	-0,055	0,107	1,076		Algorithm converged.	0,857	1,350	0,5295		0,930		Algorithm converged.	0,741	1,167
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	663	36,6	239	36,0	643	35,3	235	36,5	0,98		Algorithm converged.	0,78	1,23	-0,005		Algorithm converged.	-0,057	0,047	0,986		Algorithm converged.	0,854	1,139	0,8512	0,6876	1,014		Algorithm converged.	0,878	1,171
		Positive (ER and/or PgR positive)	697	38,5	251	36,0	681	37,4	259	38,0	0,92		Algorithm converged.	0,74	1,14	-0,020		Algorithm converged.	-0,071	0,031	0,947		Algorithm converged.	0,825	1,087	0,4374		1,056		Algorithm converged.	0,920	1,212
	Geographical region II	USA/Canada	178	9,8	68	38,2	155	8,5	49	31,6	1,34		Algorithm converged.	0,85	2,11	0,066		Algorithm converged.	-0,036	0,168	1,208		Algorithm converged.	0,897	1,627	0,2123	0,0299	0,828		Algorithm converged.	0,615	1,114
		Western Europe	587	32,4	220	37,5	574	31,5	203	35,4	1,10		Algorithm converged.	0,86	1,39	0,021		Algorithm converged.	-0,034	0,076	1,060		Algorithm converged.	0,910	1,234	0,4548		0,944		Algorithm converged.	0,810	1,099
		Asia Pacific	414	22,9	152	36,7	428	23,5	175	40,9	0,84		Algorithm converged.	0,64	1,11	-0,042		Algorithm converged.	-0,107	0,024	0,898		Algorithm converged.	0,757	1,065	0,2151		1,114		Algorithm converged.	0,939	1,320
		Latin America	34	1,9	13	38,2	36	2,0	14	38,9	0,97		Algorithm converged.	0,37	2,55	-0,007		Algorithm converged.	-0,235	0,222	0,983		Algorithm converged.	0,544	1,777	0,9552		1,017		Algorithm converged.	0,563	1,838
		Other	147	8,1	37	25,2	131	7,2	53	40,5	0,50		Algorithm converged.	0,30	0,82	-0,153		Algorithm converged.	-0,262	-0,043	0,622		Algorithm converged.	0,439	0,881	0,0075		1,607		Algorithm converged.	1,135	2,276
	Protocol version	Protocol A	956	52,8	337	35,3	915	50,2	339	37,0	0,93		Algorithm converged.	0,77	1,12	-0,018		Algorithm converged.	-0,062	0,026	0,951		Algorithm converged.	0,843	1,073	0,4183	0,6522	1,051		Algorithm converged.	0,932	1,186
		Protocol amendment B	404	22,3	153	37,9	409	22,4	155	37,9	1,00		Algorithm converged.	0,75	1,33	0,000		Algorithm converged.	-0,067	0,066	0,999		Algorithm converged.	0,838	1,192	0,9939		1,001		Algorithm converged.	0,839	1,193

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Nodal status	0 positive nodes	257	14,2	88	34,2	257	14,1	90	35,0	0,97		Algorithm converged.	0,67	1,39	-0,008		Algorithm converged.	-0,090	0,074	0,978		Algorithm converged.	0,771	1,240	0,8529	0,9065	1,023		Algorithm converged.	0,806	1,297
		>= 1 positive nodes	1103	60,9	402	36,4	1067	58,5	404	37,9	0,94		Algorithm converged.	0,79	1,12	-0,014		Algorithm converged.	-0,055	0,026	0,963		Algorithm converged.	0,863	1,074	0,4946		1,039		Algorithm converged.	0,931	1,159
	Menopausal status at randomization	Premenopausal	661	36,5	236	35,7	659	36,1	235	35,7	1,00		Algorithm converged.	0,80	1,25	0,000		Algorithm converged.	-0,051	0,052	1,001		Algorithm converged.	0,866	1,157	0,9869	0,4908	0,999		Algorithm converged.	0,864	1,154
		Postmenopausal	695	38,4	253	36,4	659	36,1	257	39,0	0,90		Algorithm converged.	0,72	1,12	-0,026		Algorithm converged.	-0,078	0,026	0,933		Algorithm converged.	0,814	1,071	0,3245		1,071		Algorithm converged.	0,934	1,229
		Unknown/Missing	4	0,2	1	25,0	6	0,3	2	33,3	0,67		Algorithm converged.	0,04	11,29	-0,083		Algorithm converged.	-0,651	0,484	0,750		Algorithm converged.	0,098	5,768	0,7822		1,333		Algorithm converged.	0,173	10,254
	Age II	< 65	1207	66,6	431	35,7	1182	64,8	437	37,0	0,95		Algorithm converged.	0,80	1,12	-0,013		Algorithm converged.	-0,051	0,026	0,966		Algorithm converged.	0,869	1,074	0,5211	0,9723	1,035		Algorithm converged.	0,931	1,151
		>= 65	153	8,4	59	38,6	142	7,8	57	40,1	0,94		Algorithm converged.	0,59	1,49	-0,016		Algorithm converged.	-0,127	0,096	0,961		Algorithm converged.	0,724	1,275	0,7814		1,041		Algorithm converged.	0,784	1,382
	Histological grade	Grade 1	26	1,4	9	34,6	20	1,1	8	40,0	0,79		Algorithm converged.	0,24	2,65	-0,054		Algorithm converged.	-0,336	0,228	0,865		Algorithm converged.	0,408	1,838	0,7067	0,7778	1,156		Algorithm converged.	0,544	2,454
		Grade 2	426	23,5	145	34,0	406	22,3	148	36,5	0,90		Algorithm converged.	0,68	1,20	-0,024		Algorithm converged.	-0,089	0,041	0,934		Algorithm converged.	0,777	1,123	0,4659		1,071		Algorithm converged.	0,891	1,288
		Grade 3	859	47,4	321	37,4	848	46,5	316	37,3	1,00		Algorithm converged.	0,83	1,22	0,001		Algorithm converged.	-0,045	0,047	1,003		Algorithm converged.	0,887	1,134	0,9643		0,997		Algorithm converged.	0,882	1,128
		Unevaluable/Unknown/Missing	49	2,7	15	30,6	50	2,7	22	44,0	0,56		Algorithm converged.	0,25	1,28	-0,134		Algorithm converged.	-0,323	0,055	0,696		Algorithm converged.	0,412	1,176	0,1755		1,437		Algorithm converged.	0,850	2,429
	Type of surgery for primary tumor	Breast conserving surgery	546	30,1	190	34,8	517	28,4	172	33,3	1,07		Algorithm converged.	0,83	1,38	0,015		Algorithm converged.	-0,042	0,072	1,046		Algorithm converged.	0,885	1,237	0,5991	0,2413	0,956		Algorithm converged.	0,809	1,130
		Mastectomy	814	44,9	300	36,9	807	44,3	322	39,9	0,88		Algorithm converged.	0,72	1,07	-0,030		Algorithm converged.	-0,078	0,017	0,924		Algorithm converged.	0,816	1,045	0,2077		1,083		Algorithm converged.	0,957	1,225

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Tumor size	0 - < 2 cm	515	28,4	176	34,2	490	26,9	174	35,5	0,94		Algorithm converged.	0,73	1,22	-0,013		Algorithm converged.	-0,072	0,046	0,962		Algorithm converged.	0,813	1,140	0,6569	0,7670	1,039		Algorithm converged.	0,877	1,231
		>= 2 - < 5 cm	743	41,0	276	37,1	719	39,4	279	38,8	0,93		Algorithm converged.	0,75	1,15	-0,017		Algorithm converged.	-0,066	0,033	0,957		Algorithm converged.	0,840	1,091	0,5139		1,045		Algorithm converged.	0,916	1,191
		>= 5 cm	100	5,5	38	38,0	113	6,2	39	34,5	1,16		Algorithm converged.	0,66	2,04	0,035		Algorithm converged.	-0,094	0,164	1,101		Algorithm converged.	0,771	1,573	0,5968		0,908		Algorithm converged.	0,636	1,297
		Missing	2	0,1	0	0,0	2	0,1	2	100,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Loco-regional radiotherapy	Yes	1040	57,4	384	36,9	1009	55,3	361	35,8	1,05		Algorithm converged.	0,88	1,26	0,011		Algorithm converged.	-0,030	0,053	1,032		Algorithm converged.	0,920	1,157	0,5902	0,0202	0,969		Algorithm converged.	0,864	1,087
		No	320	17,7	106	33,1	315	17,3	133	42,2	0,68		Algorithm converged.	0,49	0,94	-0,091		Algorithm converged.	-0,166	-0,016	0,785		Algorithm converged.	0,641	0,960	0,0187		1,275		Algorithm converged.	1,041	1,560
	Race	White	895	49,4	315	35,2	876	48,1	311	35,5	0,99		Algorithm converged.	0,81	1,20	-0,003		Algorithm converged.	-0,048	0,041	0,991		Algorithm converged.	0,874	1,124	0,8926	0,5415	1,009		Algorithm converged.	0,889	1,144
		Black	18	1,0	6	33,3	19	1,0	9	47,4	0,56		Algorithm converged.	0,15	2,10	-0,140		Algorithm converged.	-0,453	0,172	0,704		Algorithm converged.	0,314	1,577	0,3935		1,421		Algorithm converged.	0,634	3,185
		Asian	398	22,0	148	37,2	395	21,7	162	41,0	0,85		Algorithm converged.	0,64	1,13	-0,038		Algorithm converged.	-0,106	0,030	0,907		Algorithm converged.	0,762	1,079	0,2700		1,103		Algorithm converged.	0,927	1,313
		Other	44	2,4	20	45,5	33	1,8	12	36,4	1,46		Algorithm converged.	0,58	3,68	0,091		Algorithm converged.	-0,130	0,311	1,250		Algorithm converged.	0,717	2,178	0,4310		0,800		Algorithm converged.	0,459	1,394

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC04_W15_SG.xls
26OCT2020 15:41

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Social Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO												PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk								Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	349	22,7	1590	87,2	376	23,6	0,95		Algorithm converged.	0,80	1,12	-0,009		Algorithm converged.	-0,039	0,020		0,961		Algorithm converged.	0,846	1,092	0,5462		1,040		Algorithm converged.	0,915	1,182
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	12	27,9	35	1,9	6	17,1	1,87		Algorithm converged.	0,62	5,64	0,108		Algorithm converged.	-0,076	0,291		1,628		Algorithm converged.	0,680	3,895	0,2737	0,3224	0,614		Algorithm converged.	0,257	1,470
		0 positive nodes, tumor > 1 cm	225	12,4	55	24,4	248	13,6	74	29,8	0,76		Algorithm converged.	0,51	1,14	-0,054		Algorithm converged.	-0,134	0,026		0,819		Algorithm converged.	0,608	1,104	0,1907		1,221		Algorithm converged.	0,906	1,646
		1-3 positive nodes	767	42,4	174	22,7	790	43,3	173	21,9	1,05		Algorithm converged.	0,82	1,33	0,008		Algorithm converged.	-0,033	0,049		1,036		Algorithm converged.	0,861	1,247	0,7091		0,965		Algorithm converged.	0,802	1,162
		>= 4 positive nodes	500	27,6	108	21,6	517	28,4	123	23,8	0,88		Algorithm converged.	0,66	1,18	-0,022		Algorithm converged.	-0,073	0,030		0,908		Algorithm converged.	0,723	1,140	0,4049		1,101		Algorithm converged.	0,877	1,383
	Adjuvant chemotherapy regimen	Anthracycline	1229	67,9	277	22,5	1273	69,8	303	23,8	0,93		Algorithm converged.	0,77	1,12	-0,013		Algorithm converged.	-0,046	0,020		0,947		Algorithm converged.	0,821	1,092	0,4542	0,6402	1,056		Algorithm converged.	0,915	1,218
		Non-anthracycline	306	16,9	72	23,5	317	17,4	73	23,0	1,03		Algorithm converged.	0,71	1,49	0,005		Algorithm converged.	-0,061	0,071		1,022		Algorithm converged.	0,768	1,359	0,8824		0,979		Algorithm converged.	0,736	1,302
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	748	41,3	169	22,6	751	41,2	187	24,9	0,88		Algorithm converged.	0,69	1,12	-0,023		Algorithm converged.	-0,066	0,020		0,907		Algorithm converged.	0,757	1,088	0,2944	0,3883	1,102		Algorithm converged.	0,919	1,322
		Positive (ER and/or PgR positive)	787	43,5	180	22,9	839	46,0	189	22,5	1,02		Algorithm converged.	0,81	1,29	0,003		Algorithm converged.	-0,037	0,044		1,015		Algorithm converged.	0,849	1,215	0,8682		0,985		Algorithm converged.	0,823	1,179

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	45	21,1	224	12,3	45	20,1	1,07		Algorithm converged.	0,67	1,69	0,010		Algorithm converged.	-0,066	0,086	1,052		Algorithm converged.	0,728	1,520	0,7887	0,0193	0,951		Algorithm converged.	0,658	1,374
		Western Europe	661	36,5	178	26,9	674	37,0	181	26,9	1,00		Algorithm converged.	0,79	1,28	0,001		Algorithm converged.	-0,047	0,048	1,003		Algorithm converged.	0,840	1,197	0,9756		0,997		Algorithm converged.	0,836	1,190
		Asia Pacific	461	25,5	95	20,6	487	26,7	90	18,5	1,14		Algorithm converged.	0,83	1,58	0,021		Algorithm converged.	-0,029	0,072	1,115		Algorithm converged.	0,861	1,444	0,4091		0,897		Algorithm converged.	0,692	1,162
		Latin America	38	2,1	6	15,8	42	2,3	15	35,7	0,34		Algorithm converged.	0,12	0,99	-0,199		Algorithm converged.	-0,385	-0,014	0,442		Algorithm converged.	0,191	1,023	0,0565		2,262		Algorithm converged.	0,978	5,234
		Other	162	8,9	25	15,4	163	8,9	45	27,6	0,48		Algorithm converged.	0,28	0,83	-0,122		Algorithm converged.	-0,210	-0,033	0,559		Algorithm converged.	0,361	0,866	0,0092		1,789		Algorithm converged.	1,155	2,772
	Protocol version	Protocol A	1049	57,9	230	21,9	1086	59,6	261	24,0	0,89		Algorithm converged.	0,73	1,09	-0,021		Algorithm converged.	-0,057	0,015	0,912		Algorithm converged.	0,781	1,066	0,2478	0,2432	1,096		Algorithm converged.	0,938	1,281
		Protocol amendment B	486	26,8	119	24,5	504	27,6	115	22,8	1,10		Algorithm converged.	0,82	1,47	0,017		Algorithm converged.	-0,036	0,070	1,073		Algorithm converged.	0,858	1,342	0,5369		0,932		Algorithm converged.	0,745	1,166
	Nodal status	0 positive nodes	268	14,8	67	25,0	283	15,5	80	28,3	0,85		Algorithm converged.	0,58	1,24	-0,033		Algorithm converged.	-0,106	0,041	0,884		Algorithm converged.	0,670	1,168	0,3868	0,5085	1,131		Algorithm converged.	0,856	1,494
		>= 1 positive nodes	1267	70,0	282	22,3	1307	71,7	296	22,6	0,98		Algorithm converged.	0,81	1,18	-0,004		Algorithm converged.	-0,036	0,028	0,983		Algorithm converged.	0,851	1,135	0,8126		1,018		Algorithm converged.	0,881	1,175
	Menopausal status at randomization	Premenopausal	750	41,4	159	21,2	795	43,6	178	22,4	0,93		Algorithm converged.	0,73	1,19	-0,012		Algorithm converged.	-0,053	0,029	0,947		Algorithm converged.	0,784	1,144	0,5715	0,8752	1,056		Algorithm converged.	0,874	1,276
		Postmenopausal	781	43,1	188	24,1	787	43,2	196	24,9	0,96		Algorithm converged.	0,76	1,20	-0,008		Algorithm converged.	-0,051	0,034	0,967		Algorithm converged.	0,812	1,150	0,7014		1,035		Algorithm converged.	0,869	1,231
		Unknown/Missing	4	0,2	2	50,0	8	0,4	2	25,0	3,00		Algorithm converged.	0,24	37,67	0,250		Algorithm converged.	-0,325	0,825	2,000		Algorithm converged.	0,425	9,418	0,3806		0,500		Algorithm converged.	0,106	2,355
	Age II	< 65	1356	74,9	295	21,8	1416	77,7	335	23,7	0,90		Algorithm converged.	0,75	1,07	-0,019		Algorithm converged.	-0,050	0,012	0,920		Algorithm converged.	0,801	1,055	0,2324	0,0812	1,087		Algorithm converged.	0,948	1,248
		>= 65	179	9,9	54	30,2	174	9,5	41	23,6	1,40		Algorithm converged.	0,87	2,25	0,066		Algorithm converged.	-0,026	0,158	1,280		Algorithm converged.	0,904	1,814	0,1644		0,781		Algorithm converged.	0,551	1,106

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	5	18,5	22	1,2	5	22,7	0,77		Algorithm converged.	0,19	3,11	-0,042		Algorithm converged.	-0,270	0,186	0,815		Algorithm converged.	0,270	2,459	0,7163	0,5638	1,227		Algorithm converged.	0,407	3,703
		Grade 2	472	26,1	107	22,7	485	26,6	104	21,4	1,07		Algorithm converged.	0,79	1,46	0,012		Algorithm converged.	-0,040	0,065	1,057		Algorithm converged.	0,833	1,342	0,6474		0,946		Algorithm converged.	0,745	1,200
		Grade 3	977	53,9	223	22,8	1024	56,2	257	25,1	0,88		Algorithm converged.	0,72	1,08	-0,023		Algorithm converged.	-0,060	0,015	0,909		Algorithm converged.	0,778	1,064	0,2345		1,100		Algorithm converged.	0,940	1,286
		Unevaluable/Unknown/Missing	59	3,3	14	23,7	59	3,2	10	16,9	1,52		Algorithm converged.	0,62	3,78	0,068		Algorithm converged.	-0,077	0,213	1,400		Algorithm converged.	0,677	2,896	0,3642		0,714		Algorithm converged.	0,345	1,478
	Type of surgery for primary tumor	Breast conserving surgery	606	33,5	160	26,4	599	32,9	153	25,5	1,05		Algorithm converged.	0,81	1,35	0,009		Algorithm converged.	-0,041	0,058	1,034		Algorithm converged.	0,854	1,251	0,7336	0,3026	0,967		Algorithm converged.	0,799	1,171
		Mastectomy	929	51,3	189	20,3	990	54,3	223	22,5	0,88		Algorithm converged.	0,71	1,09	-0,022		Algorithm converged.	-0,059	0,015	0,903		Algorithm converged.	0,761	1,073	0,2455		1,107		Algorithm converged.	0,932	1,315
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	565	31,2	136	24,1	580	31,8	139	24,0	1,01		Algorithm converged.	0,77	1,32	0,001		Algorithm converged.	-0,048	0,051	1,004		Algorithm converged.	0,817	1,234	0,9667	0,8028	0,996		Algorithm converged.	0,810	1,223
		>= 2 - < 5 cm	845	46,7	181	21,4	859	47,1	199	23,2	0,90		Algorithm converged.	0,72	1,14	-0,017		Algorithm converged.	-0,057	0,022	0,925		Algorithm converged.	0,774	1,104	0,3868		1,082		Algorithm converged.	0,906	1,292
		>= 5 cm	123	6,8	32	26,0	149	8,2	38	25,5	1,03		Algorithm converged.	0,60	1,77	0,005		Algorithm converged.	-0,099	0,110	1,020		Algorithm converged.	0,680	1,530	0,9233		0,980		Algorithm converged.	0,654	1,470
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1187	65,5	285	24,0	1201	65,9	288	24,0	1,00		Algorithm converged.	0,83	1,21	0,000		Algorithm converged.	-0,034	0,035	1,001		Algorithm converged.	0,868	1,155	0,9863	0,2015	0,999		Algorithm converged.	0,866	1,152
		No	348	19,2	64	18,4	389	21,3	88	22,6	0,77		Algorithm converged.	0,54	1,11	-0,042		Algorithm converged.	-0,100	0,016	0,813		Algorithm converged.	0,610	1,084	0,1583		1,230		Algorithm converged.	0,923	1,640
	Race	White	1014	56,0	241	23,8	1056	57,9	266	25,2	0,93		Algorithm converged.	0,76	1,13	-0,014		Algorithm converged.	-0,051	0,023	0,944		Algorithm converged.	0,811	1,098	0,4522	0,0939	1,060		Algorithm converged.	0,911	1,233

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	4	19,0	27	1,5	6	22,2	0,82		Algorithm converged.	0,20	3,40	-0,032		Algorithm converged.	-0,262	0,198	0,857		Algorithm converged.	0,277	2,652	0,7891		1,167		Algorithm converged.	0,377	3,609
		Asian	449	24,8	95	21,2	459	25,2	85	18,5	1,18		Algorithm converged.	0,85	1,64	0,026		Algorithm converged.	-0,025	0,078	1,143		Algorithm converged.	0,879	1,485	0,3191		0,875		Algorithm converged.	0,673	1,138
		Other	47	2,6	9	19,1	47	2,6	19	40,4	0,35		Algorithm converged.	0,14	0,89	-0,213		Algorithm converged.	-0,393	-0,033	0,474		Algorithm converged.	0,239	0,937	0,0318		2,111		Algorithm converged.	1,067	4,177
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1360	75,1	209	15,4	1323	72,6	237	17,9	0,83		Algorithm converged.	0,68	1,02	-0,025		Algorithm converged.	-0,054	0,003	0,858		Algorithm converged.	0,724	1,017	0,0769		1,166		Algorithm converged.	0,984	1,382
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	4	9,1	35	1,9	4	11,4	0,78		Algorithm converged.	0,18	3,35	-0,023		Algorithm converged.	-0,159	0,112	0,795		Algorithm converged.	0,214	2,957	0,7326	-	1,257		Algorithm converged.	0,338	4,673
		0 positive nodes, tumor > 1 cm	213	11,8	33	15,5	222	12,2	36	16,2	0,95		Algorithm converged.	0,57	1,59	-0,007		Algorithm converged.	-0,076	0,061	0,955		Algorithm converged.	0,619	1,474	0,8365		1,047		Algorithm converged.	0,679	1,614
		1-3 positive nodes	692	38,2	114	16,5	654	35,9	111	17,0	0,96		Algorithm converged.	0,72	1,28	-0,005		Algorithm converged.	-0,045	0,035	0,971		Algorithm converged.	0,765	1,232	0,8065		1,030		Algorithm converged.	0,812	1,308
		>= 4 positive nodes	411	22,7	58	14,1	412	22,6	86	20,9	0,62		Algorithm converged.	0,43	0,90	-0,068		Algorithm converged.	-0,119	-0,016	0,676		Algorithm converged.	0,499	0,916	0,0115		1,479		Algorithm converged.	1,092	2,004
	Adjuvant chemotherapy regimen	Anthracycline	1085	59,9	171	15,8	1062	58,3	191	18,0	0,85		Algorithm converged.	0,68	1,07	-0,022		Algorithm converged.	-0,054	0,009	0,876		Algorithm converged.	0,726	1,058	0,1691	0,6176	1,141		Algorithm converged.	0,945	1,377
		Non-anthracycline	275	15,2	38	13,8	261	14,3	46	17,6	0,75		Algorithm converged.	0,47	1,20	-0,038		Algorithm converged.	-0,100	0,024	0,784		Algorithm converged.	0,528	1,164	0,2272		1,275		Algorithm converged.	0,859	1,893
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	663	36,6	98	14,8	643	35,3	106	16,5	0,88		Algorithm converged.	0,65	1,18	-0,017		Algorithm converged.	-0,056	0,022	0,897		Algorithm converged.	0,697	1,154	0,3968	0,6407	1,115		Algorithm converged.	0,867	1,435

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	697	38,5	111	15,9	680	37,3	131	19,3	0,79		Algorithm converged.	0,60	1,05	-0,033		Algorithm converged.	-0,074	0,007	0,827		Algorithm converged.	0,657	1,040	0,1043		1,210		Algorithm converged.	0,961	1,522
	Geographical region II	USA/Canada	178	9,8	23	12,9	155	8,5	22	14,2	0,90		Algorithm converged.	0,48	1,68	-0,013		Algorithm converged.	-0,087	0,061	0,910		Algorithm converged.	0,529	1,567	0,7348	-	1,098		Algorithm converged.	0,638	1,891
		Western Europe	587	32,4	112	19,1	573	31,4	117	20,4	0,92		Algorithm converged.	0,69	1,23	-0,013		Algorithm converged.	-0,059	0,032	0,934		Algorithm converged.	0,741	1,179	0,5669		1,070		Algorithm converged.	0,848	1,350
		Asia Pacific	414	22,9	57	13,8	428	23,5	67	15,7	0,86		Algorithm converged.	0,59	1,26	-0,019		Algorithm converged.	-0,067	0,029	0,880		Algorithm converged.	0,635	1,219	0,4406		1,137		Algorithm converged.	0,820	1,576
		Latin America	34	1,9	2	5,9	36	2,0	6	16,7	0,31		Algorithm converged.	0,06	1,67	-0,108		Algorithm converged.	-0,253	0,037	0,353		Algorithm converged.	0,076	1,630	0,1822		2,833		Algorithm converged.	0,613	13,086
		Other	147	8,1	15	10,2	131	7,2	25	19,1	0,48		Algorithm converged.	0,24	0,96	-0,089		Algorithm converged.	-0,172	-0,006	0,535		Algorithm converged.	0,295	0,970	0,0393		1,870		Algorithm converged.	1,031	3,392
	Protocol version	Protocol A	956	52,8	134	14,0	914	50,1	160	17,5	0,77		Algorithm converged.	0,60	0,99	-0,035		Algorithm converged.	-0,068	-0,002	0,801		Algorithm converged.	0,648	0,989	0,0388	0,2516	1,249		Algorithm converged.	1,011	1,542
		Protocol amendment B	404	22,3	75	18,6	409	22,4	77	18,8	0,98		Algorithm converged.	0,69	1,40	-0,003		Algorithm converged.	-0,056	0,051	0,986		Algorithm converged.	0,740	1,314	0,9237		1,014		Algorithm converged.	0,761	1,351
	Nodal status	0 positive nodes	257	14,2	37	14,4	257	14,1	40	15,6	0,91		Algorithm converged.	0,56	1,48	-0,012		Algorithm converged.	-0,073	0,050	0,925		Algorithm converged.	0,612	1,397	0,7109	0,6909	1,081		Algorithm converged.	0,716	1,633
		>= 1 positive nodes	1103	60,9	172	15,6	1066	58,5	197	18,5	0,81		Algorithm converged.	0,65	1,02	-0,029		Algorithm converged.	-0,061	0,003	0,844		Algorithm converged.	0,700	1,017	0,0742		1,185		Algorithm converged.	0,984	1,428
	Menopausal status at randomization	Premenopausal	661	36,5	104	15,7	658	36,1	123	18,7	0,81		Algorithm converged.	0,61	1,08	-0,030		Algorithm converged.	-0,070	0,011	0,842		Algorithm converged.	0,664	1,068	0,1554	0,8314	1,188		Algorithm converged.	0,937	1,507
		Postmenopausal	695	38,4	105	15,1	659	36,1	114	17,3	0,85		Algorithm converged.	0,64	1,14	-0,022		Algorithm converged.	-0,061	0,017	0,873		Algorithm converged.	0,685	1,113	0,2742		1,145		Algorithm converged.	0,898	1,460
		Unknown/Missing	4	0,2	0	0,0	6	0,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Age II	< 65	1207	66,6	182	15,1	1181	64,8	213	18,0	0,81		Algorithm converged.	0,65	1,00	-0,030		Algorithm converged.	-0,059	0,000	0,836		Algorithm converged.	0,698	1,002	0,0523	0,4122	1,196		Algorithm converged.	0,998	1,433
		>= 65	153	8,4	27	17,6	142	7,8	24	16,9	1,05		Algorithm converged.	0,58	1,93	0,007		Algorithm converged.	-0,079	0,094	1,044		Algorithm converged.	0,633	1,722	0,8657		0,958		Algorithm converged.	0,581	1,579
	Histological grade	Grade 1	26	1,4	5	19,2	20	1,1	4	20,0	0,95		Algorithm converged.	0,22	4,13	-0,008		Algorithm converged.	-0,239	0,224	0,962		Algorithm converged.	0,296	3,124	0,9480	-	1,040		Algorithm converged.	0,320	3,379
		Grade 2	426	23,5	60	14,1	405	22,2	74	18,3	0,73		Algorithm converged.	0,51	1,06	-0,042		Algorithm converged.	-0,092	0,008	0,771		Algorithm converged.	0,564	1,053	0,1022		1,297		Algorithm converged.	0,949	1,773
		Grade 3	859	47,4	136	15,8	848	46,5	151	17,8	0,87		Algorithm converged.	0,67	1,12	-0,020		Algorithm converged.	-0,055	0,016	0,889		Algorithm converged.	0,720	1,098	0,2759		1,125		Algorithm converged.	0,910	1,389
		Unevaluable/Unknown/Missing	49	2,7	8	16,3	50	2,7	8	16,0	1,02		Algorithm converged.	0,35	2,99	0,003		Algorithm converged.	-0,142	0,148	1,020		Algorithm converged.	0,416	2,503	0,9648		0,980		Algorithm converged.	0,400	2,404
	Type of surgery for primary tumor	Breast conserving surgery	546	30,1	100	18,3	516	28,3	85	16,5	1,14		Algorithm converged.	0,83	1,56	0,018		Algorithm converged.	-0,027	0,064	1,112		Algorithm converged.	0,855	1,446	0,4294	0,0111	0,899		Algorithm converged.	0,691	1,170
		Mastectomy	814	44,9	109	13,4	807	44,3	152	18,8	0,67		Algorithm converged.	0,51	0,87	-0,054		Algorithm converged.	-0,090	-0,019	0,711		Algorithm converged.	0,567	0,891	0,0031		1,407		Algorithm converged.	1,122	1,763
	Tumor size	0 - < 2 cm	515	28,4	71	13,8	490	26,9	77	15,7	0,86		Algorithm converged.	0,60	1,22	-0,019		Algorithm converged.	-0,063	0,025	0,877		Algorithm converged.	0,651	1,182	0,3890	0,7664	1,140		Algorithm converged.	0,846	1,535
		>= 2 - < 5 cm	743	41,0	126	17,0	718	39,4	140	19,5	0,84		Algorithm converged.	0,65	1,10	-0,025		Algorithm converged.	-0,065	0,014	0,870		Algorithm converged.	0,700	1,081	0,2089		1,150		Algorithm converged.	0,925	1,429
		>= 5 cm	100	5,5	12	12,0	113	6,2	20	17,7	0,63		Algorithm converged.	0,29	1,37	-0,057		Algorithm converged.	-0,152	0,038	0,678		Algorithm converged.	0,349	1,316	0,2508		1,475		Algorithm converged.	0,760	2,863
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1040	57,4	175	16,8	1008	55,3	189	18,8	0,88		Algorithm converged.	0,70	1,10	-0,019		Algorithm converged.	-0,052	0,014	0,897		Algorithm converged.	0,745	1,081	0,2554	0,2704	1,114		Algorithm converged.	0,925	1,343
		No	320	17,7	34	10,6	315	17,3	48	15,2	0,66		Algorithm converged.	0,41	1,06	-0,046		Algorithm converged.	-0,098	0,006	0,697		Algorithm converged.	0,462	1,052	0,0854		1,434		Algorithm converged.	0,951	2,163

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Race	White	895	49,4	147	16,4	875	48,0	166	19,0	0,84		Algorithm converged.	0,66	1,07	-0,025		Algorithm converged.	-0,061	0,010	0,866		Algorithm converged.	0,708	1,059	0,1608	-	1,155		Algorithm converged.	0,944	1,413
		Black	18	1,0	2	11,1	19	1,0	3	15,8	0,67		Algorithm converged.	0,10	4,54	-0,047		Algorithm converged.	-0,266	0,172	0,704		Algorithm converged.	0,133	3,735	0,6799		1,421		Algorithm converged.	0,268	7,541
		Asian	398	22,0	55	13,8	395	21,7	62	15,7	0,86		Algorithm converged.	0,58	1,28	-0,019		Algorithm converged.	-0,068	0,031	0,880		Algorithm converged.	0,630	1,231	0,4566		1,136		Algorithm converged.	0,812	1,588
		Other	44	2,4	5	11,4	33	1,8	6	18,2	0,58		Algorithm converged.	0,16	2,08	-0,068		Algorithm converged.	-0,230	0,093	0,625		Algorithm converged.	0,209	1,873	0,4013		1,600		Algorithm converged.	0,534	4,795
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC05_W15_SG.xls
26OCT2020 15:44

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1535	84,8	268	17,5	1591	87,3	252	15,8	1,12		Algorithm converged.	0,93	1,36	0,016		Algorithm converged.	-0,010	0,042		1,102		Algorithm converged.	0,942	1,290	0,2242		0,907		Algorithm converged.	0,775	1,061
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	5	11,6	35	1,9	3	8,6	1,40		Algorithm converged.	0,31	6,33	0,031		Algorithm converged.	-0,103	0,164		1,357		Algorithm converged.	0,348	5,286	0,6603	-	0,737		Algorithm converged.	0,189	2,872
		0 positive nodes, tumor > 1 cm	224	12,4	33	14,7	248	13,6	46	18,5	0,76		Algorithm converged.	0,47	1,24	-0,038		Algorithm converged.	-0,105	0,029		0,794		Algorithm converged.	0,528	1,196	0,2697		1,259		Algorithm converged.	0,836	1,895
		1-3 positive nodes	768	42,4	147	19,1	792	43,4	127	16,0	1,24		Algorithm converged.	0,95	1,61	0,031		Algorithm converged.	-0,007	0,069		1,194		Algorithm converged.	0,962	1,481	0,1077		0,838		Algorithm converged.	0,675	1,039
		>= 4 positive nodes	500	27,6	83	16,6	516	28,3	76	14,7	1,15		Algorithm converged.	0,82	1,62	0,019		Algorithm converged.	-0,026	0,063		1,127		Algorithm converged.	0,847	1,500	0,4121		0,887		Algorithm converged.	0,667	1,181
	Adjuvant chemotherapy regimen	Anthracycline	1230	67,9	220	17,9	1275	69,9	207	16,2	1,12		Algorithm converged.	0,91	1,38	0,017		Algorithm converged.	-0,013	0,046		1,102		Algorithm converged.	0,927	1,310	0,2722	0,9882	0,908		Algorithm converged.	0,764	1,079
		Non-anthracycline	305	16,8	48	15,7	316	17,3	45	14,2	1,12		Algorithm converged.	0,72	1,75	0,015		Algorithm converged.	-0,041	0,071		1,105		Algorithm converged.	0,760	1,608	0,6014		0,905		Algorithm converged.	0,622	1,317
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	748	41,3	110	14,7	750	41,1	107	14,3	1,04		Algorithm converged.	0,78	1,38	0,004		Algorithm converged.	-0,031	0,040		1,031		Algorithm converged.	0,806	1,318	0,8092	0,4543	0,970		Algorithm converged.	0,758	1,241
		Positive (ER and/or PgR positive)	787	43,5	158	20,1	841	46,1	145	17,2	1,21		Algorithm converged.	0,94	1,55	0,028		Algorithm converged.	-0,010	0,066		1,164		Algorithm converged.	0,950	1,427	0,1424		0,859		Algorithm converged.	0,701	1,052

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	215	11,9	44	20,5	224	12,3	32	14,3	1,54		Algorithm converged.	0,94	2,54	0,062		Algorithm converged.	-0,009	0,133	1,433		Algorithm converged.	0,946	2,170	0,0897	-	0,698		Algorithm converged.	0,461	1,057
		Western Europe	659	36,4	155	23,5	675	37,0	141	20,9	1,16		Algorithm converged.	0,90	1,51	0,026		Algorithm converged.	-0,018	0,071	1,126		Algorithm converged.	0,921	1,377	0,2479		0,888		Algorithm converged.	0,726	1,086
		Asia Pacific	461	25,5	51	11,1	488	26,8	51	10,5	1,07		Algorithm converged.	0,71	1,61	0,006		Algorithm converged.	-0,033	0,046	1,059		Algorithm converged.	0,734	1,527	0,7609		0,945		Algorithm converged.	0,655	1,363
		Latin America	38	2,1	2	5,3	42	2,3	4	9,5	0,53		Algorithm converged.	0,09	3,06	-0,043		Algorithm converged.	-0,156	0,071	0,553		Algorithm converged.	0,107	2,848	0,4784		1,810		Algorithm converged.	0,351	9,325
		Other	162	8,9	16	9,9	162	8,9	24	14,8	0,63		Algorithm converged.	0,32	1,24	-0,049		Algorithm converged.	-0,121	0,022	0,667		Algorithm converged.	0,368	1,207	0,1809		1,500		Algorithm converged.	0,828	2,717
	Protocol version	Protocol A	1048	57,9	174	16,6	1088	59,7	173	15,9	1,05		Algorithm converged.	0,84	1,33	0,007		Algorithm converged.	-0,024	0,038	1,044		Algorithm converged.	0,861	1,266	0,6600	0,3373	0,958		Algorithm converged.	0,790	1,161
		Protocol amendment B	487	26,9	94	19,3	503	27,6	79	15,7	1,28		Algorithm converged.	0,92	1,78	0,036		Algorithm converged.	-0,011	0,083	1,229		Algorithm converged.	0,936	1,613	0,1373		0,814		Algorithm converged.	0,620	1,068
	Nodal status	0 positive nodes	267	14,7	38	14,2	283	15,5	49	17,3	0,79		Algorithm converged.	0,50	1,26	-0,031		Algorithm converged.	-0,092	0,030	0,822		Algorithm converged.	0,557	1,213	0,3236	0,1034	1,217		Algorithm converged.	0,824	1,796
		>= 1 positive nodes	1268	70,0	230	18,1	1308	71,7	203	15,5	1,21		Algorithm converged.	0,98	1,48	0,026		Algorithm converged.	-0,003	0,055	1,169		Algorithm converged.	0,984	1,388	0,0760		0,856		Algorithm converged.	0,720	1,016
	Menopausal status at randomization	Premenopausal	751	41,5	152	20,2	797	43,7	143	17,9	1,16		Algorithm converged.	0,90	1,50	0,023		Algorithm converged.	-0,016	0,062	1,128		Algorithm converged.	0,919	1,385	0,2503	0,7548	0,886		Algorithm converged.	0,722	1,089
		Postmenopausal	780	43,1	116	14,9	786	43,1	109	13,9	1,09		Algorithm converged.	0,82	1,44	0,010		Algorithm converged.	-0,025	0,045	1,072		Algorithm converged.	0,842	1,366	0,5712		0,932		Algorithm converged.	0,732	1,188
		Unknown/Missing	4	0,2	0	0,0	8	0,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	1356	74,9	236	17,4	1416	77,7	228	16,1	1,10		Algorithm converged.	0,90	1,34	0,013		Algorithm converged.	-0,015	0,041	1,081		Algorithm converged.	0,915	1,276	0,3586	0,4733	0,925		Algorithm converged.	0,784	1,092
		>= 65	179	9,9	32	17,9	175	9,6	24	13,7	1,37		Algorithm converged.	0,77	2,44	0,042		Algorithm converged.	-0,034	0,117	1,304		Algorithm converged.	0,801	2,120	0,2856		0,767		Algorithm converged.	0,472	1,248

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	5	18,5	22	1,2	3	13,6	1,44		Algorithm converged.	0,30	6,83	0,049		Algorithm converged.	-0,156	0,254	1,358		Algorithm converged.	0,364	5,063	0,6486	-	0,736		Algorithm converged.	0,197	2,746
		Grade 2	473	26,1	80	16,9	487	26,7	78	16,0	1,07		Algorithm converged.	0,76	1,50	0,009		Algorithm converged.	-0,038	0,056	1,056		Algorithm converged.	0,794	1,404	0,7079		0,947		Algorithm converged.	0,712	1,259
		Grade 3	976	53,9	177	18,1	1023	56,1	162	15,8	1,18		Algorithm converged.	0,93	1,49	0,023		Algorithm converged.	-0,010	0,056	1,145		Algorithm converged.	0,943	1,391	0,1713		0,873		Algorithm converged.	0,719	1,060
		Unevaluable/Unknown/Missing	59	3,3	6	10,2	59	3,2	9	15,3	0,63		Algorithm converged.	0,21	1,89	-0,051		Algorithm converged.	-0,171	0,069	0,667		Algorithm converged.	0,253	1,755	0,4116		1,500		Algorithm converged.	0,570	3,949
	Type of surgery for primary tumor	Breast conserving surgery	605	33,4	130	21,5	596	32,7	115	19,3	1,14		Algorithm converged.	0,86	1,52	0,022		Algorithm converged.	-0,024	0,067	1,114		Algorithm converged.	0,890	1,393	0,3463	0,8325	0,898		Algorithm converged.	0,718	1,123
		Mastectomy	930	51,4	138	14,8	994	54,5	137	13,8	1,09		Algorithm converged.	0,84	1,41	0,011		Algorithm converged.	-0,021	0,042	1,077		Algorithm converged.	0,865	1,340	0,5084		0,929		Algorithm converged.	0,746	1,156
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	566	31,3	96	17,0	580	31,8	86	14,8	1,17		Algorithm converged.	0,85	1,61	0,021		Algorithm converged.	-0,021	0,064	1,144		Algorithm converged.	0,876	1,494	0,3237	0,9248	0,874		Algorithm converged.	0,669	1,142
		>= 2 - < 5 cm	844	46,6	145	17,2	859	47,1	133	15,5	1,13		Algorithm converged.	0,88	1,46	0,017		Algorithm converged.	-0,018	0,052	1,110		Algorithm converged.	0,895	1,376	0,3438		0,901		Algorithm converged.	0,727	1,118
		>= 5 cm	123	6,8	27	22,0	150	8,2	32	21,3	1,04		Algorithm converged.	0,58	1,85	0,006		Algorithm converged.	-0,092	0,104	1,029		Algorithm converged.	0,654	1,619	0,9017		0,972		Algorithm converged.	0,618	1,529
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1186	65,5	223	18,8	1202	65,9	190	15,8	1,23		Algorithm converged.	1,00	1,53	0,030		Algorithm converged.	0,000	0,060	1,190		Algorithm converged.	0,997	1,419	0,0534	0,0552	0,841		Algorithm converged.	0,705	1,003
		No	349	19,3	45	12,9	389	21,3	62	15,9	0,78		Algorithm converged.	0,52	1,18	-0,030		Algorithm converged.	-0,081	0,020	0,809		Algorithm converged.	0,567	1,154	0,2427		1,236		Algorithm converged.	0,866	1,764
	Race	White	1013	55,9	213	21,0	1056	57,9	195	18,5	1,18		Algorithm converged.	0,95	1,46	0,026		Algorithm converged.	-0,009	0,060	1,139		Algorithm converged.	0,957	1,355	0,1437	-	0,878		Algorithm converged.	0,738	1,045
		Black	21	1,2	1	4,8	27	1,5	6	22,2	0,18		Algorithm converged.	0,02	1,59	-0,175		Algorithm converged.	-0,356	0,007	0,214		Algorithm converged.	0,028	1,646	0,1386		4,667		Algorithm converged.	0,608	35,845
		Asian	450	24,8	50	11,1	460	25,2	48	10,4	1,07		Algorithm converged.	0,71	1,63	0,007		Algorithm converged.	-0,034	0,047	1,065		Algorithm converged.	0,732	1,548	0,7422		0,939		Algorithm converged.	0,646	1,365
		Other	47	2,6	4	8,5	47	2,6	3	6,4	1,36		Algorithm converged.	0,29	6,46	0,021		Algorithm converged.	-0,085	0,127	1,333		Algorithm converged.	0,315	5,635	0,6956		0,750		Algorithm converged.	0,177	3,170
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1358	75,0	182	13,4	1321	72,5	198	15,0	0,88		Algorithm converged.	0,71	1,09	-0,016		Algorithm converged.	-0,042	0,011	0,894		Algorithm converged.	0,742	1,077	0,2396		1,118		Algorithm converged.	0,928	1,348
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	6	14,0	35	1,9	4	11,4	1,26		Algorithm converged.	0,33	4,86	0,025		Algorithm converged.	-0,123	0,173	1,221		Algorithm converged.	0,374	3,989	0,7410	0,4347	0,819		Algorithm converged.	0,251	2,676
		0 positive nodes, tumor > 1 cm	211	11,7	28	13,3	221	12,1	29	13,1	1,01		Algorithm converged.	0,58	1,77	0,001		Algorithm converged.	-0,062	0,065	1,011		Algorithm converged.	0,623	1,641	0,9638		0,989		Algorithm converged.	0,610	1,604
		1-3 positive nodes	695	38,4	96	13,8	653	35,8	92	14,1	0,98		Algorithm converged.	0,72	1,33	-0,003		Algorithm converged.	-0,040	0,034	0,980		Algorithm converged.	0,752	1,278	0,8838		1,020		Algorithm converged.	0,782	1,330
		>= 4 positive nodes	409	22,6	52	12,7	412	22,6	73	17,7	0,68		Algorithm converged.	0,46	0,99	-0,050		Algorithm converged.	-0,099	-0,001	0,718		Algorithm converged.	0,517	0,996	0,0475		1,394		Algorithm converged.	1,004	1,935
	Adjuvant chemotherapy regimen	Anthracycline	1083	59,8	140	12,9	1062	58,3	162	15,3	0,82		Algorithm converged.	0,65	1,05	-0,023		Algorithm converged.	-0,053	0,006	0,847		Algorithm converged.	0,687	1,045	0,1219	0,2695	1,180		Algorithm converged.	0,957	1,455

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	275	15,2	42	15,3	259	14,2	36	13,9	1,12		Algorithm converged.	0,69	1,81	0,014		Algorithm converged.	-0,046	0,074	1,099		Algorithm converged.	0,728	1,658	0,6537		0,910		Algorithm converged.	0,603	1,373
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	661	36,5	79	12,0	642	35,2	83	12,9	0,91		Algorithm converged.	0,66	1,27	-0,010		Algorithm converged.	-0,046	0,026	0,924		Algorithm converged.	0,693	1,233	0,5933	0,7642	1,082		Algorithm converged.	0,811	1,443
		Positive (ER and/or PgR positive)	697	38,5	103	14,8	679	37,2	115	16,9	0,85		Algorithm converged.	0,64	1,14	-0,022		Algorithm converged.	-0,060	0,017	0,873		Algorithm converged.	0,684	1,114	0,2733		1,146		Algorithm converged.	0,898	1,463
	Geographical region II	USA/Canada	179	9,9	28	15,6	155	8,5	23	14,8	1,06		Algorithm converged.	0,58	1,94	0,008		Algorithm converged.	-0,069	0,085	1,054		Algorithm converged.	0,634	1,752	0,8387	-	0,949		Algorithm converged.	0,571	1,576
		Western Europe	584	32,2	101	17,3	572	31,4	100	17,5	0,99		Algorithm converged.	0,73	1,34	-0,002		Algorithm converged.	-0,046	0,042	0,989		Algorithm converged.	0,769	1,272	0,9328		1,011		Algorithm converged.	0,786	1,300
		Asia Pacific	415	22,9	40	9,6	428	23,5	47	11,0	0,86		Algorithm converged.	0,55	1,35	-0,013		Algorithm converged.	-0,054	0,028	0,878		Algorithm converged.	0,589	1,309	0,5222		1,139		Algorithm converged.	0,764	1,699
		Latin America	34	1,9	3	8,8	36	2,0	4	11,1	0,77		Algorithm converged.	0,16	3,74	-0,023		Algorithm converged.	-0,163	0,117	0,794		Algorithm converged.	0,192	3,291	0,7506		1,259		Algorithm converged.	0,304	5,218
		Other	146	8,1	10	6,8	130	7,1	24	18,5	0,32		Algorithm converged.	0,15	0,71	-0,116		Algorithm converged.	-0,194	-0,038	0,371		Algorithm converged.	0,184	0,746	0,0054		2,695		Algorithm converged.	1,340	5,421
	Protocol version	Protocol A	954	52,7	124	13,0	914	50,1	125	13,7	0,94		Algorithm converged.	0,72	1,23	-0,007		Algorithm converged.	-0,038	0,024	0,950		Algorithm converged.	0,754	1,198	0,6664	0,3893	1,052		Algorithm converged.	0,835	1,326
		Protocol amendment B	404	22,3	58	14,4	407	22,3	73	17,9	0,77		Algorithm converged.	0,53	1,12	-0,036		Algorithm converged.	-0,086	0,015	0,800		Algorithm converged.	0,584	1,098	0,1675		1,249		Algorithm converged.	0,911	1,714
	Nodal status	0 positive nodes	254	14,0	34	13,4	256	14,0	33	12,9	1,04		Algorithm converged.	0,62	1,75	0,005		Algorithm converged.	-0,054	0,064	1,038		Algorithm converged.	0,665	1,623	0,8685	0,4669	0,963		Algorithm converged.	0,616	1,505
		>= 1 positive nodes	1104	61,0	148	13,4	1065	58,4	165	15,5	0,84		Algorithm converged.	0,66	1,07	-0,021		Algorithm converged.	-0,050	0,009	0,865		Algorithm converged.	0,705	1,062	0,1672		1,156		Algorithm converged.	0,941	1,419
	Menopausal status at randomization	Premenopausal	662	36,6	92	13,9	657	36,0	102	15,5	0,88		Algorithm converged.	0,65	1,19	-0,016		Algorithm converged.	-0,055	0,022	0,895		Algorithm converged.	0,690	1,161	0,4043	0,9797	1,117		Algorithm converged.	0,861	1,449

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	692	38,2	89	12,9	658	36,1	95	14,4	0,87		Algorithm converged.	0,64	1,19	-0,016		Algorithm converged.	-0,052	0,021	0,891		Algorithm converged.	0,681	1,165	0,3991		1,123		Algorithm converged.	0,858	1,469
		Unknown/Missing	4	0,2	1	25,0	6	0,3	1	16,7	1,67		Algorithm converged.	0,07	37,73	0,083		Algorithm converged.	-0,435	0,602	1,500		Algorithm converged.	0,127	17,667	0,7473		0,667		Algorithm converged.	0,057	7,852
	Age II	< 65	1205	66,5	157	13,0	1181	64,8	179	15,2	0,84		Algorithm converged.	0,67	1,06	-0,021		Algorithm converged.	-0,049	0,007	0,860		Algorithm converged.	0,705	1,049	0,1357	0,2567	1,163		Algorithm converged.	0,954	1,419
		>= 65	153	8,4	25	16,3	140	7,7	19	13,6	1,24		Algorithm converged.	0,65	2,37	0,028		Algorithm converged.	-0,054	0,109	1,204		Algorithm converged.	0,694	2,088	0,5088		0,831		Algorithm converged.	0,479	1,441
	Histological grade	Grade 1	26	1,4	5	19,2	20	1,1	5	25,0	0,71		Algorithm converged.	0,18	2,91	-0,058		Algorithm converged.	-0,301	0,185	0,769		Algorithm converged.	0,258	2,297	0,6383	0,1513	1,300		Algorithm converged.	0,435	3,882
		Grade 2	427	23,6	39	9,1	406	22,3	57	14,0	0,62		Algorithm converged.	0,40	0,95	-0,049		Algorithm converged.	-0,093	-0,006	0,651		Algorithm converged.	0,443	0,955	0,0282		1,537		Algorithm converged.	1,047	2,257
		Grade 3	856	47,3	133	15,5	845	46,4	131	15,5	1,00		Algorithm converged.	0,77	1,30	0,000		Algorithm converged.	-0,034	0,035	1,002		Algorithm converged.	0,803	1,251	0,9844		0,998		Algorithm converged.	0,799	1,245
		Unevaluable/Unknown/Missing	49	2,7	5	10,2	50	2,7	5	10,0	1,02		Algorithm converged.	0,28	3,78	0,002		Algorithm converged.	-0,117	0,121	1,020		Algorithm converged.	0,315	3,305	0,9731		0,980		Algorithm converged.	0,303	3,174
	Type of surgery for primary tumor	Breast conserving surgery	544	30,0	75	13,8	519	28,5	95	18,3	0,71		Algorithm converged.	0,51	0,99	-0,045		Algorithm converged.	-0,089	-0,001	0,753		Algorithm converged.	0,570	0,994	0,0456	0,1086	1,328		Algorithm converged.	1,006	1,753
		Mastectomy	814	44,9	107	13,1	802	44,0	103	12,8	1,03		Algorithm converged.	0,77	1,37	0,003		Algorithm converged.	-0,030	0,036	1,024		Algorithm converged.	0,795	1,317	0,8567		0,977		Algorithm converged.	0,759	1,257
	Tumor size	0 - < 2 cm	515	28,4	62	12,0	488	26,8	74	15,2	0,77		Algorithm converged.	0,53	1,10	-0,031		Algorithm converged.	-0,074	0,011	0,794		Algorithm converged.	0,580	1,087	0,1496	0,6158	1,260		Algorithm converged.	0,920	1,724
		>= 2 - < 5 cm	741	40,9	106	14,3	717	39,3	109	15,2	0,93		Algorithm converged.	0,70	1,24	-0,009		Algorithm converged.	-0,045	0,027	0,941		Algorithm converged.	0,735	1,204	0,6291		1,063		Algorithm converged.	0,830	1,360
		>= 5 cm	100	5,5	14	14,0	114	6,3	15	13,2	1,07		Algorithm converged.	0,49	2,35	0,008		Algorithm converged.	-0,084	0,100	1,064		Algorithm converged.	0,541	2,094	0,8575		0,940		Algorithm converged.	0,478	1,850
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	1038	57,3	140	13,5	1008	55,3	152	15,1	0,88		Algorithm converged.	0,69	1,13	-0,016		Algorithm converged.	-0,046	0,014	0,894		Algorithm converged.	0,723	1,106	0,3037	0,9946	1,118		Algorithm converged.	0,904	1,383
		No	320	17,7	42	13,1	313	17,2	46	14,7	0,88		Algorithm converged.	0,56	1,38	-0,016		Algorithm converged.	-0,070	0,038	0,893		Algorithm converged.	0,606	1,317	0,5680		1,120		Algorithm converged.	0,759	1,651
	Race	White	892	49,3	139	15,6	873	47,9	149	17,1	0,90		Algorithm converged.	0,70	1,15	-0,015		Algorithm converged.	-0,049	0,020	0,913		Algorithm converged.	0,739	1,128	0,3989	-	1,095		Algorithm converged.	0,887	1,353
		Black	18	1,0	1	5,6	19	1,0	3	15,8	0,31		Algorithm converged.	0,03	3,34	-0,102		Algorithm converged.	-0,297	0,093	0,352		Algorithm converged.	0,040	3,080	0,3453		2,842		Algorithm converged.	0,325	24,877
		Asian	400	22,1	37	9,3	395	21,7	43	10,9	0,83		Algorithm converged.	0,52	1,33	-0,016		Algorithm converged.	-0,058	0,025	0,850		Algorithm converged.	0,560	1,289	0,4439		1,177		Algorithm converged.	0,776	1,786
		Other	43	2,4	5	11,6	33	1,8	3	9,1	1,32		Algorithm converged.	0,29	5,95	0,025		Algorithm converged.	-0,112	0,162	1,279		Algorithm converged.	0,329	4,971	0,7223		0,782		Algorithm converged.	0,201	3,039
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC10_W15_SG.xls
26OCT2020 16:27

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	292	19,1	1580	86,7	245	15,5	1,28		Algorithm converged.	1,06	1,55	0,036		Algorithm converged.	0,009	0,062		1,229		Algorithm converged.	1,053	1,435	0,0089		0,814		Algorithm converged.	0,697	0,950
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	10	23,3	34	1,9	4	11,8	2,27		Algorithm converged.	0,64	8,02	0,115		Algorithm converged.	-0,051	0,281		1,977		Algorithm converged.	0,679	5,756	0,2114	0,1940	0,506		Algorithm converged.	0,174	1,473
		0 positive nodes, tumor > 1 cm	224	12,4	41	18,3	247	13,5	38	15,4	1,23		Algorithm converged.	0,76	2,00	0,029		Algorithm converged.	-0,039	0,097		1,190		Algorithm converged.	0,795	1,779	0,3977		0,841		Algorithm converged.	0,562	1,257
		1-3 positive nodes	768	42,4	137	17,8	787	43,2	132	16,8	1,08		Algorithm converged.	0,83	1,40	0,011		Algorithm converged.	-0,027	0,048		1,064		Algorithm converged.	0,856	1,322	0,5785		0,940		Algorithm converged.	0,757	1,169
		>= 4 positive nodes	497	27,4	104	20,9	512	28,1	71	13,9	1,64		Algorithm converged.	1,18	2,29	0,071		Algorithm converged.	0,024	0,117		1,509		Algorithm converged.	1,146	1,987	0,0034		0,663		Algorithm converged.	0,503	0,873
	Adjuvant chemotherapy regimen	Anthracycline	1227	67,8	242	19,7	1270	69,7	186	14,6	1,43		Algorithm converged.	1,16	1,77	0,051		Algorithm converged.	0,021	0,080		1,347		Algorithm converged.	1,131	1,603	0,0008	0,0221	0,743		Algorithm converged.	0,624	0,884
		Non-anthracycline	305	16,8	50	16,4	310	17,0	59	19,0	0,83		Algorithm converged.	0,55	1,26	-0,026		Algorithm converged.	-0,087	0,034		0,861		Algorithm converged.	0,612	1,213	0,3923		1,161		Algorithm converged.	0,825	1,634
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	745	41,1	142	19,1	749	41,1	112	15,0	1,34		Algorithm converged.	1,02	1,76	0,041		Algorithm converged.	0,003	0,079		1,275		Algorithm converged.	1,017	1,598	0,0353	0,6671	0,785		Algorithm converged.	0,626	0,983
		Positive (ER and/or PgR positive)	787	43,5	150	19,1	831	45,6	133	16,0	1,24		Algorithm converged.	0,96	1,60	0,031		Algorithm converged.	-0,007	0,068		1,191		Algorithm converged.	0,963	1,472	0,1065		0,840		Algorithm converged.	0,679	1,038

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	33	15,5	223	12,2	34	15,2	1,02		Algorithm converged.	0,61	1,72	0,002		Algorithm converged.	-0,065	0,070	1,016		Algorithm converged.	0,654	1,579	0,9432	0,4454	0,984		Algorithm converged.	0,633	1,529
		Western Europe	659	36,4	154	23,4	666	36,5	110	16,5	1,54		Algorithm converged.	1,17	2,02	0,069		Algorithm converged.	0,026	0,111	1,415		Algorithm converged.	1,136	1,763	0,0020		0,707		Algorithm converged.	0,567	0,880
		Asia Pacific	461	25,5	75	16,3	486	26,7	74	15,2	1,08		Algorithm converged.	0,76	1,53	0,010		Algorithm converged.	-0,036	0,057	1,068		Algorithm converged.	0,796	1,435	0,6597		0,936		Algorithm converged.	0,697	1,257
		Latin America	37	2,0	7	18,9	42	2,3	5	11,9	1,73		Algorithm converged.	0,50	5,99	0,070		Algorithm converged.	-0,090	0,230	1,589		Algorithm converged.	0,551	4,583	0,3913		0,629		Algorithm converged.	0,218	1,815
		Other	162	8,9	23	14,2	163	8,9	22	13,5	1,06		Algorithm converged.	0,56	1,99	0,007		Algorithm converged.	-0,068	0,082	1,052		Algorithm converged.	0,611	1,810	0,8549		0,951		Algorithm converged.	0,553	1,635
	Protocol version	Protocol A	1046	57,8	183	17,5	1079	59,2	173	16,0	1,11		Algorithm converged.	0,88	1,39	0,015		Algorithm converged.	-0,017	0,046	1,091		Algorithm converged.	0,903	1,319	0,3672	0,0325	0,916		Algorithm converged.	0,758	1,108
		Protocol amendment B	486	26,8	109	22,4	501	27,5	72	14,4	1,72		Algorithm converged.	1,24	2,39	0,081		Algorithm converged.	0,032	0,129	1,561		Algorithm converged.	1,191	2,045	0,0012		0,641		Algorithm converged.	0,489	0,840
	Nodal status	0 positive nodes	267	14,7	51	19,1	281	15,4	42	14,9	1,34		Algorithm converged.	0,86	2,10	0,042		Algorithm converged.	-0,021	0,104	1,278		Algorithm converged.	0,881	1,855	0,1968	0,8213	0,783		Algorithm converged.	0,539	1,136
		>= 1 positive nodes	1265	69,9	241	19,1	1299	71,3	203	15,6	1,27		Algorithm converged.	1,03	1,56	0,034		Algorithm converged.	0,005	0,064	1,219		Algorithm converged.	1,029	1,445	0,0223		0,820		Algorithm converged.	0,692	0,972
	Menopausal status at randomization	Premenopausal	752	41,5	146	19,4	789	43,3	129	16,3	1,23		Algorithm converged.	0,95	1,60	0,031		Algorithm converged.	-0,008	0,069	1,187		Algorithm converged.	0,958	1,472	0,1168	0,6703	0,842		Algorithm converged.	0,679	1,044
		Postmenopausal	776	42,8	146	18,8	783	43,0	116	14,8	1,33		Algorithm converged.	1,02	1,74	0,040		Algorithm converged.	0,003	0,077	1,270		Algorithm converged.	1,016	1,587	0,0354		0,787		Algorithm converged.	0,630	0,984
		Unknown/Missing	4	0,2	0	0,0	8	0,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	1354	74,8	268	19,8	1407	77,2	220	15,6	1,33		Algorithm converged.	1,09	1,62	0,042		Algorithm converged.	0,013	0,070	1,266		Algorithm converged.	1,077	1,488	0,0043	0,2724	0,790		Algorithm converged.	0,672	0,929
		>= 65	178	9,8	24	13,5	173	9,5	25	14,5	0,92		Algorithm converged.	0,50	1,69	-0,010		Algorithm converged.	-0,082	0,063	0,933		Algorithm converged.	0,555	1,569	0,7937		1,072		Algorithm converged.	0,637	1,802

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	6	22,2	22	1,2	2	9,1	2,86		Algorithm converged.	0,51	15,85	0,131		Algorithm converged.	-0,066	0,329	2,444		Algorithm converged.	0,547	10,934	0,2422	-	0,409		Algorithm converged.	0,091	1,830
		Grade 2	468	25,8	87	18,6	481	26,4	81	16,8	1,13		Algorithm converged.	0,81	1,57	0,017		Algorithm converged.	-0,031	0,066	1,104		Algorithm converged.	0,839	1,453	0,4804		0,906		Algorithm converged.	0,688	1,192
		Grade 3	978	54,0	191	19,5	1019	55,9	155	15,2	1,35		Algorithm converged.	1,07	1,71	0,043		Algorithm converged.	0,010	0,076	1,284		Algorithm converged.	1,059	1,557	0,0111		0,779		Algorithm converged.	0,642	0,945
		Unevaluable/Unknown/Missing	59	3,3	8	13,6	58	3,2	7	12,1	1,14		Algorithm converged.	0,39	3,39	0,015		Algorithm converged.	-0,106	0,136	1,123		Algorithm converged.	0,436	2,898	0,8097		0,890		Algorithm converged.	0,345	2,296
	Type of surgery for primary tumor	Breast conserving surgery	603	33,3	156	25,9	593	32,5	127	21,4	1,28		Algorithm converged.	0,98	1,67	0,045		Algorithm converged.	-0,004	0,093	1,208		Algorithm converged.	0,984	1,483	0,0708	0,9362	0,828		Algorithm converged.	0,674	1,016
		Mastectomy	929	51,3	136	14,6	986	54,1	118	12,0	1,26		Algorithm converged.	0,97	1,64	0,027		Algorithm converged.	-0,004	0,057	1,223		Algorithm converged.	0,972	1,539	0,0855		0,817		Algorithm converged.	0,650	1,029
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	563	31,1	112	19,9	576	31,6	97	16,8	1,23		Algorithm converged.	0,91	1,66	0,031		Algorithm converged.	-0,014	0,075	1,181		Algorithm converged.	0,924	1,510	0,1840	0,7296	0,847		Algorithm converged.	0,662	1,082
		>= 2 - < 5 cm	845	46,7	158	18,7	854	46,8	123	14,4	1,37		Algorithm converged.	1,06	1,77	0,043		Algorithm converged.	0,008	0,078	1,298		Algorithm converged.	1,046	1,611	0,0177		0,770		Algorithm converged.	0,621	0,956
		>= 5 cm	122	6,7	22	18,0	148	8,1	25	16,9	1,08		Algorithm converged.	0,58	2,03	0,011		Algorithm converged.	-0,080	0,103	1,068		Algorithm converged.	0,634	1,796	0,8056		0,937		Algorithm converged.	0,557	1,576
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1184	65,4	260	22,0	1192	65,4	205	17,2	1,35		Algorithm converged.	1,10	1,66	0,048		Algorithm converged.	0,016	0,079	1,277		Algorithm converged.	1,083	1,505	0,0036	0,1342	0,783		Algorithm converged.	0,664	0,923
		No	348	19,2	32	9,2	388	21,3	40	10,3	0,88		Algorithm converged.	0,54	1,44	-0,011		Algorithm converged.	-0,054	0,032	0,892		Algorithm converged.	0,573	1,387	0,6119		1,121		Algorithm converged.	0,721	1,744
	Race	White	1012	55,9	203	20,1	1046	57,4	163	15,6	1,36		Algorithm converged.	1,08	1,71	0,045		Algorithm converged.	0,012	0,078	1,287		Algorithm converged.	1,068	1,552	0,0082	0,3369	0,777		Algorithm converged.	0,644	0,937

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	3	14,3	27	1,5	7	25,9	0,48		Algorithm converged.	0,11	2,12	-0,116		Algorithm converged.	-0,339	0,107	0,551		Algorithm converged.	0,162	1,878	0,3409		1,815		Algorithm converged.	0,532	6,187
		Asian	449	24,8	77	17,1	459	25,2	71	15,5	1,13		Algorithm converged.	0,80	1,61	0,017		Algorithm converged.	-0,031	0,065	1,109		Algorithm converged.	0,825	1,489	0,4932		0,902		Algorithm converged.	0,672	1,212
		Other	46	2,5	8	17,4	47	2,6	4	8,5	2,26		Algorithm converged.	0,63	8,12	0,089		Algorithm converged.	-0,047	0,224	2,043		Algorithm converged.	0,661	6,321	0,2149		0,489		Algorithm converged.	0,158	1,514
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1355	74,8	154	11,4	1318	72,3	141	10,7	1,07		Algorithm converged.	0,84	1,36	0,007		Algorithm converged.	-0,017	0,030	1,062		Algorithm converged.	0,856	1,318	0,5821		0,941		Algorithm converged.	0,759	1,168
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	8	18,2	35	1,9	1	2,9	7,56		Algorithm converged.	0,90	63,65	0,153		Algorithm converged.	0,027	0,280	6,364		Algorithm converged.	0,835	48,497	0,0741	-	0,157		Algorithm converged.	0,021	1,198
		0 positive nodes, tumor > 1 cm	210	11,6	28	13,3	222	12,2	16	7,2	1,98		Algorithm converged.	1,04	3,78	0,061		Algorithm converged.	0,004	0,118	1,850		Algorithm converged.	1,031	3,319	0,0391		0,541		Algorithm converged.	0,301	0,970
		1-3 positive nodes	693	38,3	66	9,5	651	35,7	74	11,4	0,82		Algorithm converged.	0,58	1,17	-0,018		Algorithm converged.	-0,051	0,014	0,838		Algorithm converged.	0,612	1,147	0,2696		1,194		Algorithm converged.	0,872	1,634
		>= 4 positive nodes	408	22,5	52	12,7	410	22,5	50	12,2	1,05		Algorithm converged.	0,69	1,59	0,005		Algorithm converged.	-0,040	0,051	1,045		Algorithm converged.	0,727	1,503	0,8119		0,957		Algorithm converged.	0,665	1,376
	Adjuvant chemotherapy regimen	Anthracycline	1082	59,7	127	11,7	1060	58,1	99	9,3	1,29		Algorithm converged.	0,98	1,70	0,024		Algorithm converged.	-0,002	0,050	1,257		Algorithm converged.	0,980	1,612	0,0718	0,0051	0,796		Algorithm converged.	0,620	1,020

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	273	15,1	27	9,9	258	14,2	42	16,3	0,56		Algorithm converged.	0,34	0,95	-0,064		Algorithm converged.	-0,121	-0,007	0,608		Algorithm converged.	0,386	0,955	0,0309		1,646		Algorithm converged.	1,047	2,588
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	660	36,4	75	11,4	642	35,2	65	10,1	1,14		Algorithm converged.	0,80	1,62	0,012		Algorithm converged.	-0,021	0,046	1,122		Algorithm converged.	0,820	1,536	0,4710	0,6353	0,891		Algorithm converged.	0,651	1,219
		Positive (ER and/or PgR positive)	695	38,4	79	11,4	676	37,1	76	11,2	1,01		Algorithm converged.	0,72	1,41	0,001		Algorithm converged.	-0,032	0,035	1,011		Algorithm converged.	0,752	1,360	0,9421		0,989		Algorithm converged.	0,735	1,331
	Geographical region II	USA/Canada	178	9,8	16	9,0	154	8,4	13	8,4	1,07		Algorithm converged.	0,50	2,30	0,005		Algorithm converged.	-0,055	0,066	1,065		Algorithm converged.	0,529	2,143	0,8603	-	0,939		Algorithm converged.	0,467	1,890
		Western Europe	582	32,1	88	15,1	570	31,3	74	13,0	1,19		Algorithm converged.	0,86	1,67	0,021		Algorithm converged.	-0,019	0,061	1,165		Algorithm converged.	0,874	1,551	0,2974		0,859		Algorithm converged.	0,645	1,144
		Asia Pacific	415	22,9	38	9,2	427	23,4	41	9,6	0,95		Algorithm converged.	0,60	1,51	-0,004		Algorithm converged.	-0,044	0,035	0,954		Algorithm converged.	0,626	1,452	0,8247		1,049		Algorithm converged.	0,689	1,596
		Latin America	33	1,8	3	9,1	36	2,0	1	2,8	3,50		Algorithm converged.	0,35	35,44	0,063		Algorithm converged.	-0,049	0,175	3,273		Algorithm converged.	0,358	29,933	0,2938		0,306		Algorithm converged.	0,033	2,795
		Other	147	8,1	9	6,1	131	7,2	12	9,2	0,65		Algorithm converged.	0,26	1,59	-0,030		Algorithm converged.	-0,093	0,032	0,668		Algorithm converged.	0,291	1,535	0,3423		1,496		Algorithm converged.	0,651	3,437
	Protocol version	Protocol A	953	52,6	106	11,1	911	50,0	90	9,9	1,14		Algorithm converged.	0,85	1,54	0,012		Algorithm converged.	-0,015	0,040	1,126		Algorithm converged.	0,863	1,469	0,3821	0,4722	0,888		Algorithm converged.	0,681	1,159
		Protocol amendment B	402	22,2	48	11,9	407	22,3	51	12,5	0,95		Algorithm converged.	0,62	1,44	-0,006		Algorithm converged.	-0,051	0,039	0,953		Algorithm converged.	0,659	1,379	0,7978		1,049		Algorithm converged.	0,725	1,518
	Nodal status	0 positive nodes	254	14,0	36	14,2	257	14,1	17	6,6	2,33		Algorithm converged.	1,27	4,27	0,076		Algorithm converged.	0,023	0,128	2,143		Algorithm converged.	1,236	3,714	0,0066	0,0041	0,467		Algorithm converged.	0,269	0,809
		>= 1 positive nodes	1101	60,8	118	10,7	1061	58,2	124	11,7	0,91		Algorithm converged.	0,69	1,19	-0,010		Algorithm converged.	-0,036	0,017	0,917		Algorithm converged.	0,723	1,163	0,4749		1,090		Algorithm converged.	0,860	1,383
	Menopausal status at randomization	Premenopausal	662	36,6	79	11,9	654	35,9	73	11,2	1,08		Algorithm converged.	0,77	1,51	0,008		Algorithm converged.	-0,027	0,042	1,069		Algorithm converged.	0,793	1,442	0,6616	0,9460	0,935		Algorithm converged.	0,693	1,262

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	689	38,0	75	10,9	658	36,1	68	10,3	1,06		Algorithm converged.	0,75	1,50	0,006		Algorithm converged.	-0,027	0,038	1,053		Algorithm converged.	0,772	1,437	0,7429		0,949		Algorithm converged.	0,696	1,295
		Unknown/Missing	4	0,2	0	0,0	6	0,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	1203	66,4	141	11,7	1177	64,6	125	10,6	1,12		Algorithm converged.	0,87	1,44	0,011		Algorithm converged.	-0,014	0,036	1,104		Algorithm converged.	0,880	1,385	0,3946	0,3049	0,906		Algorithm converged.	0,722	1,137
		>= 65	152	8,4	13	8,6	141	7,7	16	11,3	0,73		Algorithm converged.	0,34	1,58	-0,028		Algorithm converged.	-0,097	0,041	0,754		Algorithm converged.	0,376	1,510	0,4252		1,327		Algorithm converged.	0,662	2,659
	Histological grade	Grade 1	26	1,4	5	19,2	20	1,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Grade 2	425	23,5	39	9,2	404	22,2	50	12,4	0,72		Algorithm converged.	0,46	1,11	-0,032		Algorithm converged.	-0,074	0,010	0,741		Algorithm converged.	0,499	1,102	0,1387		1,349		Algorithm converged.	0,908	2,004
		Grade 3	855	47,2	105	12,3	844	46,3	88	10,4	1,20		Algorithm converged.	0,89	1,62	0,019		Algorithm converged.	-0,012	0,049	1,178		Algorithm converged.	0,902	1,538	0,2293		0,849		Algorithm converged.	0,650	1,109
		Unevaluable/Unknown/Missing	49	2,7	5	10,2	50	2,7	3	6,0	1,78		Algorithm converged.	0,40	7,89	0,042		Algorithm converged.	-0,065	0,149	1,701		Algorithm converged.	0,430	6,733	0,4494		0,588		Algorithm converged.	0,149	2,328
	Type of surgery for primary tumor	Breast conserving surgery	540	29,8	78	14,4	517	28,4	69	13,3	1,10		Algorithm converged.	0,77	1,55	0,011		Algorithm converged.	-0,031	0,053	1,082		Algorithm converged.	0,801	1,462	0,6062	0,8469	0,924		Algorithm converged.	0,684	1,248
		Mastectomy	815	45,0	76	9,3	801	43,9	72	9,0	1,04		Algorithm converged.	0,74	1,46	0,003		Algorithm converged.	-0,025	0,031	1,037		Algorithm converged.	0,763	1,411	0,8147		0,964		Algorithm converged.	0,709	1,311

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Tumor size	0 - < 2 cm	514	28,4	60	11,7	487	26,7	52	10,7	1,11		Algorithm converged.	0,75	1,64	0,010		Algorithm converged.	-0,029	0,049	1,093		Algorithm converged.	0,770	1,551	0,6177	0,9617	0,915		Algorithm converged.	0,645	1,298
		>= 2 - < 5 cm	739	40,8	81	11,0	716	39,3	73	10,2	1,08		Algorithm converged.	0,78	1,51	0,008		Algorithm converged.	-0,024	0,039	1,075		Algorithm converged.	0,797	1,450	0,6354		0,930		Algorithm converged.	0,690	1,255
		>= 5 cm	100	5,5	13	13,0	113	6,2	15	13,3	0,98		Algorithm converged.	0,44	2,17	-0,003		Algorithm converged.	-0,094	0,088	0,979		Algorithm converged.	0,490	1,957	0,9529		1,021		Algorithm converged.	0,511	2,040
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1035	57,2	136	13,1	1004	55,1	122	12,2	1,09		Algorithm converged.	0,84	1,42	0,010		Algorithm converged.	-0,019	0,039	1,081		Algorithm converged.	0,861	1,359	0,5022	0,6562	0,925		Algorithm converged.	0,736	1,162
		No	320	17,7	18	5,6	314	17,2	19	6,1	0,93		Algorithm converged.	0,48	1,80	-0,004		Algorithm converged.	-0,041	0,032	0,930		Algorithm converged.	0,497	1,738	0,8191		1,076		Algorithm converged.	0,575	2,011
	Race	White	891	49,2	112	12,6	870	47,7	97	11,1	1,15		Algorithm converged.	0,86	1,53	0,014		Algorithm converged.	-0,016	0,044	1,127		Algorithm converged.	0,873	1,455	0,3572	-	0,887		Algorithm converged.	0,687	1,145
		Black	18	1,0	0	0,0	19	1,0	4	21,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	0,9999		>999		Algorithm converged.	0,000	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asian	399	22,0	37	9,3	395	21,7	39	9,9	0,93		Algorithm converged.	0,58	1,50	-0,006		Algorithm converged.	-0,047	0,035	0,939		Algorithm converged.	0,612	1,441	0,7738		1,065		Algorithm converged.	0,694	1,633
		Other	42	2,3	4	9,5	33	1,8	1	3,0	3,37		Algorithm converged.	0,36	31,68	0,065		Algorithm converged.	-0,041	0,171	3,143		Algorithm converged.	0,369	26,802	0,2950		0,318		Algorithm converged.	0,037	2,713
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC11_W15_SG.xls
26OCT2020 16:30

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1532	84,6	201	13,1	1581	86,7	228	14,4	0,90		Algorithm converged.	0,73	1,10	-0,013		Algorithm converged.	-0,037	0,011		0,910		Algorithm converged.	0,763	1,085	0,2927		1,099		Algorithm converged.	0,922	1,311
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	8	18,6	34	1,9	6	17,6	1,07		Algorithm converged.	0,33	3,43	0,010		Algorithm converged.	-0,163	0,183		1,054		Algorithm converged.	0,404	2,748	0,9139	0,5101	0,949		Algorithm converged.	0,364	2,473
		0 positive nodes, tumor > 1 cm	224	12,4	29	12,9	246	13,5	25	10,2	1,31		Algorithm converged.	0,74	2,32	0,028		Algorithm converged.	-0,030	0,086		1,274		Algorithm converged.	0,770	2,107	0,3458		0,785		Algorithm converged.	0,475	1,299
		1-3 positive nodes	768	42,4	89	11,6	788	43,2	110	14,0	0,81		Algorithm converged.	0,60	1,09	-0,024		Algorithm converged.	-0,057	0,009		0,830		Algorithm converged.	0,639	1,078	0,1624		1,205		Algorithm converged.	0,928	1,564
		>= 4 positive nodes	497	27,4	75	15,1	513	28,1	87	17,0	0,87		Algorithm converged.	0,62	1,22	-0,019		Algorithm converged.	-0,064	0,027		0,890		Algorithm converged.	0,670	1,181	0,4190		1,124		Algorithm converged.	0,847	1,492
	Adjuvant chemotherapy regimen	Anthracycline	1227	67,8	149	12,1	1270	69,7	180	14,2	0,84		Algorithm converged.	0,66	1,06	-0,020		Algorithm converged.	-0,047	0,006		0,857		Algorithm converged.	0,700	1,049	0,1345	0,2267	1,167		Algorithm converged.	0,953	1,429
		Non-anthracycline	305	16,8	52	17,0	311	17,1	48	15,4	1,13		Algorithm converged.	0,73	1,73	0,016		Algorithm converged.	-0,042	0,074		1,105		Algorithm converged.	0,771	1,582	0,5870		0,905		Algorithm converged.	0,632	1,296
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	745	41,1	99	13,3	748	41,0	93	12,4	1,08		Algorithm converged.	0,80	1,46	0,009		Algorithm converged.	-0,025	0,043		1,069		Algorithm converged.	0,821	1,392	0,6216	0,1093	0,936		Algorithm converged.	0,718	1,219
		Positive (ER and/or PgR positive)	787	43,5	102	13,0	833	45,7	135	16,2	0,77		Algorithm converged.	0,58	1,02	-0,032		Algorithm converged.	-0,067	0,002		0,800		Algorithm converged.	0,630	1,015	0,0656		1,250		Algorithm converged.	0,986	1,586

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	24	11,3	223	12,2	27	12,1	0,92		Algorithm converged.	0,51	1,65	-0,008		Algorithm converged.	-0,069	0,052	0,931		Algorithm converged.	0,555	1,560	0,7851	-	1,075		Algorithm converged.	0,641	1,802
		Western Europe	659	36,4	100	15,2	667	36,6	114	17,1	0,87		Algorithm converged.	0,65	1,16	-0,019		Algorithm converged.	-0,059	0,020	0,888		Algorithm converged.	0,694	1,135	0,3433		1,126		Algorithm converged.	0,881	1,440
		Asia Pacific	461	25,5	57	12,4	486	26,7	53	10,9	1,15		Algorithm converged.	0,77	1,72	0,015		Algorithm converged.	-0,026	0,055	1,134		Algorithm converged.	0,798	1,612	0,4840		0,882		Algorithm converged.	0,621	1,254
		Latin America	37	2,0	5	13,5	42	2,3	3	7,1	2,03		Algorithm converged.	0,45	9,16	0,064		Algorithm converged.	-0,071	0,199	1,892		Algorithm converged.	0,485	7,382	0,3587		0,529		Algorithm converged.	0,135	2,062
		Other	162	8,9	15	9,3	163	8,9	31	19,0	0,43		Algorithm converged.	0,22	0,84	-0,098		Algorithm converged.	-0,173	-0,023	0,487		Algorithm converged.	0,273	0,867	0,0145		2,054		Algorithm converged.	1,154	3,657
	Protocol version	Protocol A	1046	57,8	142	13,6	1078	59,1	152	14,1	0,96		Algorithm converged.	0,75	1,22	-0,005		Algorithm converged.	-0,035	0,024	0,963		Algorithm converged.	0,779	1,191	0,7263	0,3512	1,039		Algorithm converged.	0,840	1,284
		Protocol amendment B	486	26,8	59	12,1	503	27,6	76	15,1	0,78		Algorithm converged.	0,54	1,12	-0,030		Algorithm converged.	-0,072	0,013	0,803		Algorithm converged.	0,586	1,103	0,1753		1,245		Algorithm converged.	0,907	1,708
	Nodal status	0 positive nodes	267	14,7	37	13,9	280	15,4	31	11,1	1,29		Algorithm converged.	0,78	2,15	0,028		Algorithm converged.	-0,028	0,083	1,252		Algorithm converged.	0,801	1,957	0,3248	0,1249	0,799		Algorithm converged.	0,511	1,249
		>= 1 positive nodes	1265	69,9	164	13,0	1301	71,4	197	15,1	0,83		Algorithm converged.	0,67	1,04	-0,022		Algorithm converged.	-0,049	0,005	0,856		Algorithm converged.	0,706	1,038	0,1133		1,168		Algorithm converged.	0,964	1,415
	Menopausal status at randomization	Premenopausal	752	41,5	85	11,3	790	43,3	108	13,7	0,80		Algorithm converged.	0,59	1,09	-0,024		Algorithm converged.	-0,057	0,009	0,827		Algorithm converged.	0,634	1,079	0,1612	0,3395	1,209		Algorithm converged.	0,927	1,578
		Postmenopausal	776	42,8	115	14,8	783	43,0	118	15,1	0,98		Algorithm converged.	0,74	1,30	-0,003		Algorithm converged.	-0,038	0,033	0,983		Algorithm converged.	0,776	1,246	0,8896		1,017		Algorithm converged.	0,802	1,289
		Unknown/Missing	4	0,2	1	25,0	8	0,4	2	25,0	1,00		Algorithm converged.	0,06	15,99	0,000		Algorithm converged.	-0,520	0,520	1,000		Algorithm converged.	0,125	7,995	1,0000		1,000		Algorithm converged.	0,125	7,995
	Age II	< 65	1354	74,8	173	12,8	1407	77,2	197	14,0	0,90		Algorithm converged.	0,72	1,12	-0,012		Algorithm converged.	-0,038	0,013	0,913		Algorithm converged.	0,755	1,104	0,3454	0,8978	1,096		Algorithm converged.	0,906	1,325
		>= 65	178	9,8	28	15,7	174	9,5	31	17,8	0,86		Algorithm converged.	0,49	1,51	-0,021		Algorithm converged.	-0,099	0,057	0,883		Algorithm converged.	0,554	1,407	0,6007		1,133		Algorithm converged.	0,710	1,805

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	2	7,4	22	1,2	1	4,5	1,68		Algorithm converged.	0,14	19,85	0,029		Algorithm converged.	-0,103	0,160	1,630		Algorithm converged.	0,158	16,808	0,6817	-	0,614		Algorithm converged.	0,059	6,329
		Grade 2	468	25,8	64	13,7	482	26,4	73	15,1	0,89		Algorithm converged.	0,62	1,28	-0,015		Algorithm converged.	-0,059	0,030	0,903		Algorithm converged.	0,662	1,232	0,5194		1,107		Algorithm converged.	0,812	1,511
		Grade 3	978	54,0	133	13,6	1019	55,9	146	14,3	0,94		Algorithm converged.	0,73	1,21	-0,007		Algorithm converged.	-0,038	0,023	0,949		Algorithm converged.	0,763	1,180	0,6388		1,054		Algorithm converged.	0,847	1,310
		Unevaluable/Unknown/Missing	59	3,3	2	3,4	58	3,2	8	13,8	0,22		Algorithm converged.	0,04	1,08	-0,104		Algorithm converged.	-0,204	-0,004	0,246		Algorithm converged.	0,054	1,109	0,0679		4,069		Algorithm converged.	0,902	18,355
	Type of surgery for primary tumor	Breast conserving surgery	603	33,3	99	16,4	594	32,6	109	18,4	0,87		Algorithm converged.	0,65	1,18	-0,019		Algorithm converged.	-0,062	0,024	0,895		Algorithm converged.	0,699	1,146	0,3781	0,9258	1,118		Algorithm converged.	0,873	1,431
		Mastectomy	929	51,3	102	11,0	986	54,1	119	12,1	0,90		Algorithm converged.	0,68	1,19	-0,011		Algorithm converged.	-0,039	0,018	0,910		Algorithm converged.	0,709	1,167	0,4562		1,099		Algorithm converged.	0,857	1,410
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	563	31,1	69	12,3	576	31,6	81	14,1	0,85		Algorithm converged.	0,60	1,20	-0,018		Algorithm converged.	-0,057	0,021	0,872		Algorithm converged.	0,646	1,176	0,3679	0,6607	1,147		Algorithm converged.	0,851	1,548
		>= 2 - < 5 cm	845	46,7	111	13,1	855	46,9	125	14,6	0,88		Algorithm converged.	0,67	1,16	-0,015		Algorithm converged.	-0,048	0,018	0,899		Algorithm converged.	0,709	1,139	0,3767		1,113		Algorithm converged.	0,878	1,411
		>= 5 cm	122	6,7	21	17,2	148	8,1	22	14,9	1,19		Algorithm converged.	0,62	2,29	0,023		Algorithm converged.	-0,065	0,112	1,158		Algorithm converged.	0,670	2,003	0,5998		0,864		Algorithm converged.	0,499	1,494
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1184	65,4	168	14,2	1194	65,5	185	15,5	0,90		Algorithm converged.	0,72	1,13	-0,013		Algorithm converged.	-0,042	0,016	0,916		Algorithm converged.	0,755	1,111	0,3711	0,7691	1,092		Algorithm converged.	0,900	1,324
		No	348	19,2	33	9,5	387	21,2	43	11,1	0,84		Algorithm converged.	0,52	1,35	-0,016		Algorithm converged.	-0,060	0,028	0,853		Algorithm converged.	0,555	1,312	0,4700		1,172		Algorithm converged.	0,762	1,801
	Race	White	1012	55,9	135	13,3	1047	57,4	169	16,1	0,80		Algorithm converged.	0,63	1,02	-0,028		Algorithm converged.	-0,059	0,003	0,826		Algorithm converged.	0,671	1,019	0,0740	-	1,210		Algorithm converged.	0,982	1,491

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	7	33,3	27	1,5	5	18,5	2,20		Algorithm converged.	0,58	8,31	0,148		Algorithm converged.	-0,101	0,397	1,800		Algorithm converged.	0,665	4,873	0,2474		0,556		Algorithm converged.	0,205	1,504
		Asian	449	24,8	56	12,5	459	25,2	51	11,1	1,14		Algorithm converged.	0,76	1,71	0,014		Algorithm converged.	-0,028	0,056	1,122		Algorithm converged.	0,786	1,603	0,5251		0,891		Algorithm converged.	0,624	1,272
		Other	46	2,5	2	4,3	47	2,6	3	6,4	0,67		Algorithm converged.	0,11	4,19	-0,020		Algorithm converged.	-0,112	0,071	0,681		Algorithm converged.	0,119	3,890	0,6658		1,468		Algorithm converged.	0,257	8,384
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1355	74,8	176	13,0	1320	72,4	176	13,3	0,97		Algorithm converged.	0,78	1,21	-0,003		Algorithm converged.	-0,029	0,022	0,974		Algorithm converged.	0,802	1,184	0,7922		1,027		Algorithm converged.	0,845	1,247
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	44	2,4	5	11,4	35	1,9	2	5,7	2,12		Algorithm converged.	0,38	11,63	0,056		Algorithm converged.	-0,065	0,178	1,989		Algorithm converged.	0,410	9,641	0,3934	-	0,503		Algorithm converged.	0,104	2,438
		0 positive nodes, tumor > 1 cm	210	11,6	25	11,9	222	12,2	18	8,1	1,53		Algorithm converged.	0,81	2,90	0,038		Algorithm converged.	-0,019	0,095	1,468		Algorithm converged.	0,826	2,611	0,1910		0,681		Algorithm converged.	0,383	1,211
		1-3 positive nodes	693	38,3	88	12,7	652	35,8	92	14,1	0,89		Algorithm converged.	0,65	1,21	-0,014		Algorithm converged.	-0,051	0,022	0,900		Algorithm converged.	0,686	1,181	0,4474		1,111		Algorithm converged.	0,847	1,459
		>= 4 positive nodes	408	22,5	58	14,2	411	22,5	64	15,6	0,90		Algorithm converged.	0,61	1,32	-0,014		Algorithm converged.	-0,062	0,035	0,913		Algorithm converged.	0,658	1,267	0,5860		1,095		Algorithm converged.	0,789	1,520
	Adjuvant chemotherapy regimen	Anthracycline	1082	59,7	134	12,4	1061	58,2	138	13,0	0,95		Algorithm converged.	0,73	1,22	-0,006		Algorithm converged.	-0,034	0,022	0,952		Algorithm converged.	0,763	1,189	0,6654	0,6819	1,050		Algorithm converged.	0,841	1,311

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	273	15,1	42	15,4	259	14,2	38	14,7	1,06		Algorithm converged.	0,66	1,70	0,007		Algorithm converged.	-0,054	0,068	1,049		Algorithm converged.	0,700	1,571	0,8182		0,954		Algorithm converged.	0,636	1,429
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	660	36,4	84	12,7	642	35,2	59	9,2	1,44		Algorithm converged.	1,01	2,05	0,035		Algorithm converged.	0,002	0,069	1,385		Algorithm converged.	1,011	1,897	0,0426	0,0038	0,722		Algorithm converged.	0,527	0,989
		Positive (ER and/or PgR positive)	695	38,4	92	13,2	678	37,2	117	17,3	0,73		Algorithm converged.	0,54	0,98	-0,040		Algorithm converged.	-0,078	-0,002	0,767		Algorithm converged.	0,596	0,987	0,0390		1,304		Algorithm converged.	1,013	1,677
	Geographical region II	USA/Canada	178	9,8	22	12,4	154	8,4	21	13,6	0,89		Algorithm converged.	0,47	1,70	-0,013		Algorithm converged.	-0,085	0,060	0,906		Algorithm converged.	0,519	1,583	0,7297	-	1,103		Algorithm converged.	0,632	1,927
		Western Europe	582	32,1	93	16,0	572	31,4	95	16,6	0,95		Algorithm converged.	0,70	1,31	-0,006		Algorithm converged.	-0,049	0,036	0,962		Algorithm converged.	0,741	1,250	0,7724		1,039		Algorithm converged.	0,800	1,350
		Asia Pacific	415	22,9	37	8,9	427	23,4	38	8,9	1,00		Algorithm converged.	0,62	1,61	0,000		Algorithm converged.	-0,038	0,039	1,002		Algorithm converged.	0,650	1,543	0,9933		0,998		Algorithm converged.	0,648	1,538
		Latin America	33	1,8	3	9,1	36	2,0	2	5,6	1,70		Algorithm converged.	0,27	10,87	0,035		Algorithm converged.	-0,088	0,159	1,636		Algorithm converged.	0,291	9,191	0,5759		0,611		Algorithm converged.	0,109	3,432
		Other	147	8,1	21	14,3	131	7,2	20	15,3	0,93		Algorithm converged.	0,48	1,80	-0,010		Algorithm converged.	-0,093	0,074	0,936		Algorithm converged.	0,532	1,647	0,8178		1,069		Algorithm converged.	0,607	1,881
	Protocol version	Protocol A	953	52,6	129	13,5	911	50,0	111	12,2	1,13		Algorithm converged.	0,86	1,48	0,014		Algorithm converged.	-0,017	0,044	1,111		Algorithm converged.	0,877	1,408	0,3841	0,0541	0,900		Algorithm converged.	0,710	1,141
		Protocol amendment B	402	22,2	47	11,7	409	22,4	65	15,9	0,70		Algorithm converged.	0,47	1,05	-0,042		Algorithm converged.	-0,089	0,005	0,736		Algorithm converged.	0,519	1,043	0,0848		1,359		Algorithm converged.	0,959	1,927
	Nodal status	0 positive nodes	254	14,0	30	11,8	257	14,1	20	7,8	1,59		Algorithm converged.	0,88	2,88	0,040		Algorithm converged.	-0,011	0,092	1,518		Algorithm converged.	0,886	2,601	0,1289	0,0753	0,659		Algorithm converged.	0,385	1,129
		>= 1 positive nodes	1101	60,8	146	13,3	1063	58,3	156	14,7	0,89		Algorithm converged.	0,70	1,13	-0,014		Algorithm converged.	-0,043	0,015	0,904		Algorithm converged.	0,733	1,114	0,3426		1,107		Algorithm converged.	0,898	1,364
	Menopausal status at randomization	Premenopausal	662	36,6	84	12,7	655	35,9	86	13,1	0,96		Algorithm converged.	0,70	1,33	-0,004		Algorithm converged.	-0,041	0,032	0,966		Algorithm converged.	0,730	1,279	0,8114	0,9088	1,035		Algorithm converged.	0,782	1,370

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Postmenopausal	689	38,0	92	13,4	659	36,1	89	13,5	0,99		Algorithm converged.	0,72	1,35	-0,002		Algorithm converged.	-0,038	0,035	0,989		Algorithm converged.	0,754	1,297	0,9345		1,011		Algorithm converged.	0,771	1,326
		Unknown/Missing	4	0,2	0	0,0	6	0,3	1	16,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1203	66,4	154	12,8	1178	64,6	156	13,2	0,96		Algorithm converged.	0,76	1,22	-0,004		Algorithm converged.	-0,031	0,023	0,967		Algorithm converged.	0,785	1,190	0,7490	0,8410	1,034		Algorithm converged.	0,841	1,273
		>= 65	152	8,4	22	14,5	142	7,8	20	14,1	1,03		Algorithm converged.	0,54	1,99	0,004		Algorithm converged.	-0,076	0,084	1,028		Algorithm converged.	0,587	1,800	0,9241		0,973		Algorithm converged.	0,555	1,705
	Histological grade	Grade 1	26	1,4	7	26,9	20	1,1	3	15,0	2,09		Algorithm converged.	0,46	9,38	0,119		Algorithm converged.	-0,112	0,351	1,795		Algorithm converged.	0,530	6,082	0,3475	0,5525	0,557		Algorithm converged.	0,164	1,888
		Grade 2	425	23,5	55	12,9	405	22,2	57	14,1	0,91		Algorithm converged.	0,61	1,35	-0,011		Algorithm converged.	-0,058	0,035	0,920		Algorithm converged.	0,652	1,298	0,6331		1,088		Algorithm converged.	0,771	1,535
		Grade 3	855	47,2	110	12,9	845	46,4	109	12,9	1,00		Algorithm converged.	0,75	1,32	0,000		Algorithm converged.	-0,032	0,032	0,997		Algorithm converged.	0,779	1,277	0,9834		1,003		Algorithm converged.	0,783	1,284
		Unevaluable/Unknown/Missing	49	2,7	4	8,2	50	2,7	7	14,0	0,55		Algorithm converged.	0,15	2,00	-0,058		Algorithm converged.	-0,181	0,065	0,583		Algorithm converged.	0,182	1,867	0,3636		1,715		Algorithm converged.	0,536	5,490
	Type of surgery for primary tumor	Breast conserving surgery	540	29,8	83	15,4	518	28,4	85	16,4	0,93		Algorithm converged.	0,67	1,29	-0,010		Algorithm converged.	-0,054	0,034	0,937		Algorithm converged.	0,710	1,236	0,6440	0,7200	1,068		Algorithm converged.	0,809	1,409
		Mastectomy	815	45,0	93	11,4	802	44,0	91	11,3	1,01		Algorithm converged.	0,74	1,37	0,001		Algorithm converged.	-0,030	0,032	1,006		Algorithm converged.	0,766	1,320	0,9675		0,994		Algorithm converged.	0,758	1,305

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Tumor size	0 - < 2 cm	514	28,4	68	13,2	487	26,7	58	11,9	1,13		Algorithm converged.	0,78	1,64	0,013		Algorithm converged.	-0,028	0,054	1,111		Algorithm converged.	0,800	1,542	0,5295	0,6487	0,900		Algorithm converged.	0,649	1,249
		>= 2 - < 5 cm	739	40,8	94	12,7	718	39,4	100	13,9	0,90		Algorithm converged.	0,67	1,22	-0,012		Algorithm converged.	-0,047	0,023	0,913		Algorithm converged.	0,703	1,187	0,4977		1,095		Algorithm converged.	0,842	1,423
		>= 5 cm	100	5,5	14	14,0	113	6,2	17	15,0	0,92		Algorithm converged.	0,43	1,98	-0,010		Algorithm converged.	-0,105	0,084	0,931		Algorithm converged.	0,484	1,790	0,8294		1,075		Algorithm converged.	0,559	2,067
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1035	57,2	141	13,6	1006	55,2	152	15,1	0,89		Algorithm converged.	0,69	1,14	-0,015		Algorithm converged.	-0,045	0,016	0,902		Algorithm converged.	0,729	1,115	0,3387	0,0901	1,109		Algorithm converged.	0,897	1,371
		No	320	17,7	35	10,9	314	17,2	24	7,6	1,48		Algorithm converged.	0,86	2,56	0,033		Algorithm converged.	-0,012	0,078	1,431		Algorithm converged.	0,872	2,349	0,1564		0,699		Algorithm converged.	0,426	1,147
	Race	White	891	49,2	135	15,2	872	47,8	133	15,3	0,99		Algorithm converged.	0,77	1,29	-0,001		Algorithm converged.	-0,035	0,033	0,993		Algorithm converged.	0,797	1,238	0,9530	-	1,007		Algorithm converged.	0,807	1,255
		Black	18	1,0	3	16,7	19	1,0	5	26,3	0,56		Algorithm converged.	0,11	2,79	-0,096		Algorithm converged.	-0,359	0,166	0,633		Algorithm converged.	0,176	2,273	0,4836		1,579		Algorithm converged.	0,440	5,667
		Asian	399	22,0	33	8,3	395	21,7	37	9,4	0,87		Algorithm converged.	0,53	1,43	-0,011		Algorithm converged.	-0,050	0,028	0,883		Algorithm converged.	0,564	1,382	0,5862		1,133		Algorithm converged.	0,723	1,773
		Other	42	2,3	5	11,9	33	1,8	1	3,0	4,32		Algorithm converged.	0,48	38,97	0,089		Algorithm converged.	-0,025	0,203	3,929		Algorithm converged.	0,482	32,019	0,2012		0,255		Algorithm converged.	0,031	2,075
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC12_W15_SG.xls
26OCT2020 16:33

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Increase Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	57	3,1	10	17,5	54	3,0	16	29,6	0,51		Algorithm converged.	0,21	1,24	-0,121		Algorithm converged.	-0,278	0,036		0,592		Algorithm converged.	0,295	1,189	0,1405			1,689		Algorithm converged.	0,841	3,391
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	0	0,0	0	0,0	1	<0.1	1	100,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	3	0,2	0	0,0	10	0,5	2	20,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,000		Algorithm converged.	0,000	NE	1,0000			>999		Algorithm converged.	0,000	NE
		1-3 positive nodes	32	1,8	6	18,8	27	1,5	13	48,1	0,25		Algorithm converged.	0,08	0,80	-0,294		Algorithm converged.	-0,526	-0,062		0,389		Algorithm converged.	0,171	0,885	0,0243			2,568		Algorithm converged.	1,130	5,834
		>= 4 positive nodes	22	1,2	4	18,2	16	0,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	Adjuvant chemotherapy regimen	Anthracycline	40	2,2	4	10,0	43	2,4	11	25,6	0,32		Algorithm converged.	0,09	1,12	-0,156		Algorithm converged.	-0,316	0,004		0,391		Algorithm converged.	0,135	1,129	0,0825	0,3264		2,558		Algorithm converged.	0,886	7,386

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Non-anthracycline	17	0,9	6	35,3	11	0,6	5	45,5	0,65		Algorithm converged.	0,14	3,08	-0,102		Algorithm converged.	-0,473	0,270	0,776		Algorithm converged.	0,312	1,935	0,5870		1,288		Algorithm converged.	0,517	3,209
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	27	1,5	5	18,5	32	1,8	10	31,3	0,50		Algorithm converged.	0,15	1,70	-0,127		Algorithm converged.	-0,345	0,090	0,593		Algorithm converged.	0,231	1,522	0,2770	0,9659	1,687		Algorithm converged.	0,657	4,335
		Positive (ER and/or PgR positive)	30	1,7	5	16,7	22	1,2	6	27,3	0,53		Algorithm converged.	0,14	2,04	-0,106		Algorithm converged.	-0,335	0,123	0,611		Algorithm converged.	0,214	1,749	0,3587		1,636		Algorithm converged.	0,572	4,684
	Geographical region II	USA/Canada	9	0,5	3	33,3	6	0,3	1	16,7	2,50		Algorithm converged.	0,19	32,19	0,167		Algorithm converged.	-0,262	0,595	2,000		Algorithm converged.	0,267	14,982	0,4999	-	0,500		Algorithm converged.	0,067	3,745
		Western Europe	16	0,9	3	18,8	18	1,0	7	38,9	0,36		Algorithm converged.	0,08	1,75	-0,201		Algorithm converged.	-0,497	0,094	0,482		Algorithm converged.	0,149	1,558	0,2228		2,074		Algorithm converged.	0,642	6,702
		Asia Pacific	25	1,4	2	8,0	21	1,2	4	19,0	0,37		Algorithm converged.	0,06	2,26	-0,110		Algorithm converged.	-0,309	0,088	0,420		Algorithm converged.	0,085	2,070	0,2865		2,381		Algorithm converged.	0,483	11,736
		Latin America	2	0,1	1	50,0	4	0,2	3	75,0	0,33		Algorithm converged.	0,01	11,94	-0,250		Algorithm converged.	-1,063	0,563	0,667		Algorithm converged.	0,149	2,979	0,5955		1,500		Algorithm converged.	0,336	6,702
		Other	5	0,3	1	20,0	5	0,3	1	20,0	1,00		Algorithm converged.	0,05	22,18	0,000		Algorithm converged.	-0,496	0,496	1,000		Algorithm converged.	0,084	11,931	1,0000		1,000		Algorithm converged.	0,084	11,931
	Protocol version	Protocol A	39	2,2	6	15,4	39	2,1	13	33,3	0,36		Algorithm converged.	0,12	1,09	-0,179		Algorithm converged.	-0,366	0,007	0,462		Algorithm converged.	0,195	1,090	0,0779	-	2,167		Algorithm converged.	0,917	5,118
		Protocol amendment B	18	1,0	4	22,2	15	0,8	3	20,0	1,14		Algorithm converged.	0,21	6,16	0,022		Algorithm converged.	-0,257	0,301	1,111		Algorithm converged.	0,294	4,205	0,8767		0,900		Algorithm converged.	0,238	3,406

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Nodal status	0 positive nodes	3	0,2	0	0,0	11	0,6	3	27,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	0,9999	-	>999		Algorithm converged.	0,000	NE
		>= 1 positive nodes	54	3,0	10	18,5	43	2,4	13	30,2	0,52		Algorithm converged.	0,20	1,35	-0,117		Algorithm converged.	-0,289	0,055	0,613		Algorithm converged.	0,298	1,259	0,1824		1,633		Algorithm converged.	0,794	3,356
	Menopausal status at randomization	Premenopausal	24	1,3	4	16,7	29	1,6	7	24,1	0,63		Algorithm converged.	0,16	2,47	-0,075		Algorithm converged.	-0,290	0,141	0,690		Algorithm converged.	0,229	2,081	0,5105	0,6677	1,448		Algorithm converged.	0,481	4,364
		Postmenopausal	33	1,8	6	18,2	25	1,4	9	36,0	0,40		Algorithm converged.	0,12	1,32	-0,178		Algorithm converged.	-0,408	0,051	0,505		Algorithm converged.	0,207	1,233	0,1337		1,980		Algorithm converged.	0,811	4,835
	Age II	< 65	51	2,8	9	17,6	49	2,7	14	28,6	0,54		Algorithm converged.	0,21	1,39	-0,109		Algorithm converged.	-0,273	0,055	0,618		Algorithm converged.	0,295	1,294	0,2018	-	1,619		Algorithm converged.	0,773	3,393
		>= 65	6	0,3	1	16,7	5	0,3	2	40,0	0,30		Algorithm converged.	0,02	4,91	-0,233		Algorithm converged.	-0,756	0,289	0,417		Algorithm converged.	0,052	3,357	0,4109		2,400		Algorithm converged.	0,298	19,337
	Histological grade	Grade 1	0	0,0	0	0,0	2	0,1	1	50,0	NE		Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Grade 2	26	1,4	4	15,4	21	1,2	5	23,8	0,58		Algorithm converged.	0,13	2,52	-0,084		Algorithm converged.	-0,313	0,145	0,646		Algorithm converged.	0,198	2,108	0,4691		1,548		Algorithm converged.	0,474	5,048
		Grade 3	30	1,7	6	20,0	29	1,6	9	31,0	0,56		Algorithm converged.	0,17	1,83	-0,110		Algorithm converged.	-0,331	0,111	0,644		Algorithm converged.	0,263	1,582	0,3376		1,552		Algorithm converged.	0,632	3,809

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unevaluable/Unknown/Missing	1	<0.1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Type of surgery for primary tumor	Breast conserving surgery	19	1,0	3	15,8	18	1,0	7	38,9	0,29		Algorithm converged.	0,06	1,40	-0,231		Algorithm converged.	-0,510	0,048	0,406		Algorithm converged.	0,124	1,333	0,1373	0,4195	2,463		Algorithm converged.	0,750	8,088
		Mastectomy	38	2,1	7	18,4	36	2,0	9	25,0	0,68		Algorithm converged.	0,22	2,06	-0,066		Algorithm converged.	-0,253	0,122	0,737		Algorithm converged.	0,307	1,770	0,4946		1,357		Algorithm converged.	0,565	3,260
	Tumor size	0 - < 2 cm	20	1,1	3	15,0	21	1,2	7	33,3	0,35		Algorithm converged.	0,08	1,62	-0,183		Algorithm converged.	-0,439	0,072	0,450		Algorithm converged.	0,135	1,503	0,1944	-	2,222		Algorithm converged.	0,665	7,422
		>= 2 - < 5 cm	30	1,7	7	23,3	27	1,5	7	25,9	0,87		Algorithm converged.	0,26	2,91	-0,026		Algorithm converged.	-0,250	0,198	0,900		Algorithm converged.	0,362	2,235	0,8204		1,111		Algorithm converged.	0,447	2,759
		>= 5 cm	7	0,4	0	0,0	6	0,3	2	33,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	44	2,4	7	15,9	36	2,0	9	25,0	0,57		Algorithm converged.	0,19	1,71	-0,091		Algorithm converged.	-0,269	0,087	0,636		Algorithm converged.	0,263	1,540	0,3163	0,9245	1,571		Algorithm converged.	0,649	3,804

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		No	13	0,7	3	23,1	18	1,0	7	38,9	0,47		Algorithm converged.	0,10	2,34	-0,158		Algorithm converged.	-0,479	0,163	0,593		Algorithm converged.	0,188	1,872	0,3734		1,685		Algorithm converged.	0,534	5,317
	Race	White	23	1,3	7	30,4	25	1,4	9	36,0	0,78		Algorithm converged.	0,23	2,60	-0,056		Algorithm converged.	-0,322	0,210	0,845		Algorithm converged.	0,376	1,899	0,6842	-	1,183		Algorithm converged.	0,527	2,657
		Black	3	0,2	1	33,3	4	0,2	1	25,0	1,50		Algorithm converged.	0,06	40,63	0,083		Algorithm converged.	-0,598	0,765	1,333		Algorithm converged.	0,129	13,743	0,8090		0,750		Algorithm converged.	0,073	7,730
		Asian	25	1,4	2	8,0	22	1,2	4	18,2	0,39		Algorithm converged.	0,06	2,38	-0,102		Algorithm converged.	-0,295	0,091	0,440		Algorithm converged.	0,089	2,174	0,3139		2,273		Algorithm converged.	0,460	11,232
		Other	5	0,3	0	0,0	3	0,2	2	66,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
		Missing	1	<0.1	0	0,0	0	0,0	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	73	4,0	18	24,7	77	4,2	20	26,0	0,93		Algorithm converged.	0,45	1,95	-0,013		Algorithm converged.	-0,152	0,126	0,949		Algorithm converged.	0,547	1,646	0,8531		1,053		Algorithm converged.	0,607	1,827
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	2	0,1	1	50,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	-	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	12	0,7	5	41,7	15	0,8	4	26,7	1,96		Algorithm converged.	0,39	9,93	0,150		Algorithm converged.	-0,208	0,508	1,562		Algorithm converged.	0,534	4,571	0,4152		0,640		Algorithm converged.	0,219	1,872
		1-3 positive nodes	30	1,7	7	23,3	35	1,9	9	25,7	0,88		Algorithm converged.	0,28	2,74	-0,024		Algorithm converged.	-0,233	0,186	0,907		Algorithm converged.	0,384	2,142	0,8245		1,102		Algorithm converged.	0,467	2,602
		>= 4 positive nodes	29	1,6	5	17,2	26	1,4	7	26,9	0,57		Algorithm converged.	0,15	2,07	-0,097		Algorithm converged.	-0,316	0,122	0,640		Algorithm converged.	0,231	1,773	0,3910		1,562		Algorithm converged.	0,564	4,323
	Adjuvant chemotherapy regimen	Anthracycline	50	2,8	7	14,0	64	3,5	16	25,0	0,49		Algorithm converged.	0,18	1,30	-0,110		Algorithm converged.	-0,253	0,033	0,560		Algorithm converged.	0,250	1,256	0,1593	0,0818	1,786		Algorithm converged.	0,796	4,004
		Non-anthracycline	23	1,3	11	47,8	13	0,7	4	30,8	2,06		Algorithm converged.	0,49	8,65	0,171		Algorithm converged.	-0,153	0,494	1,554		Algorithm converged.	0,619	3,902	0,3476		0,643		Algorithm converged.	0,256	1,615
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	35	1,9	9	25,7	44	2,4	12	27,3	0,92		Algorithm converged.	0,34	2,53	-0,016		Algorithm converged.	-0,211	0,180	0,943		Algorithm converged.	0,449	1,979	0,8764	0,9501	1,061		Algorithm converged.	0,505	2,226
		Positive (ER and/or PgR positive)	38	2,1	9	23,7	33	1,8	8	24,2	0,97		Algorithm converged.	0,33	2,89	-0,006		Algorithm converged.	-0,205	0,194	0,977		Algorithm converged.	0,426	2,241	0,9561		1,024		Algorithm converged.	0,446	2,348
	Geographical region II	USA/Canada	11	0,6	4	36,4	4	0,2	1	25,0	1,71		Algorithm converged.	0,13	22,51	0,114		Algorithm converged.	-0,397	0,624	1,455		Algorithm converged.	0,224	9,426	0,6943	-	0,688		Algorithm converged.	0,106	4,455
		Western Europe	16	0,9	4	25,0	26	1,4	8	30,8	0,75		Algorithm converged.	0,18	3,06	-0,058		Algorithm converged.	-0,334	0,219	0,813		Algorithm converged.	0,291	2,267	0,6916		1,231		Algorithm converged.	0,441	3,434
		Asia Pacific	34	1,9	9	26,5	34	1,9	5	14,7	2,09		Algorithm converged.	0,62	7,05	0,118		Algorithm converged.	-0,073	0,308	1,800		Algorithm converged.	0,673	4,817	0,2419		0,556		Algorithm converged.	0,208	1,487

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	4	0,2	0	0,0	4	0,2	3	75,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
		Other	8	0,4	1	12,5	9	0,5	3	33,3	0,29		Algorithm converged.	0,02	3,52	-0,208		Algorithm converged.	-0,592	0,176	0,375		Algorithm converged.	0,048	2,922	0,3491		2,667		Algorithm converged.	0,342	20,777
	Protocol version	Protocol A	51	2,8	12	23,5	62	3,4	17	27,4	0,81		Algorithm converged.	0,35	1,91	-0,039		Algorithm converged.	-0,200	0,122	0,858		Algorithm converged.	0,453	1,626	0,6391	-	1,165		Algorithm converged.	0,615	2,209
		Protocol amendment B	22	1,2	6	27,3	15	0,8	3	20,0	1,50		Algorithm converged.	0,31	7,25	0,073		Algorithm converged.	-0,202	0,348	1,364		Algorithm converged.	0,402	4,622	0,6185		0,733		Algorithm converged.	0,216	2,486
	Nodal status	0 positive nodes	14	0,8	6	42,9	16	0,9	4	25,0	2,25		Algorithm converged.	0,48	10,60	0,179		Algorithm converged.	-0,156	0,514	1,714		Algorithm converged.	0,605	4,861	0,3107	0,1988	0,583		Algorithm converged.	0,206	1,654
		>= 1 positive nodes	59	3,3	12	20,3	61	3,3	16	26,2	0,72		Algorithm converged.	0,31	1,68	-0,059		Algorithm converged.	-0,210	0,092	0,775		Algorithm converged.	0,402	1,496	0,4482		1,290		Algorithm converged.	0,668	2,489
	Menopausal status at randomization	Premenopausal	34	1,9	7	20,6	40	2,2	11	27,5	0,68		Algorithm converged.	0,23	2,02	-0,069		Algorithm converged.	-0,263	0,125	0,749		Algorithm converged.	0,326	1,717	0,4943	0,4415	1,336		Algorithm converged.	0,582	3,063
		Postmenopausal	39	2,2	11	28,2	37	2,0	9	24,3	1,22		Algorithm converged.	0,44	3,41	0,039		Algorithm converged.	-0,159	0,236	1,160		Algorithm converged.	0,544	2,473	0,7017		0,862		Algorithm converged.	0,404	1,839
	Age II	< 65	63	3,5	15	23,8	64	3,5	18	28,1	0,80		Algorithm converged.	0,36	1,77	-0,043		Algorithm converged.	-0,195	0,109	0,847		Algorithm converged.	0,469	1,528	0,5802	-	1,181		Algorithm converged.	0,655	2,132
		>= 65	10	0,6	3	30,0	13	0,7	2	15,4	2,36		Algorithm converged.	0,31	17,85	0,146		Algorithm converged.	-0,199	0,491	1,950		Algorithm converged.	0,398	9,543	0,4098		0,513		Algorithm converged.	0,105	2,510

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO									PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	0	0,0	0	0,0	2	0,1	1	50,0	NE		Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Grade 2	29	1,6	5	17,2	22	1,2	8	36,4	0,36		Algorithm converged.	0,10	1,33	-0,191		Algorithm converged.	-0,435	0,052	0,474		Algorithm converged.	0,180	1,251	0,1317		2,109		Algorithm converged.	0,799	5,565
		Grade 3	42	2,3	12	28,6	51	2,8	10	19,6	1,64		Algorithm converged.	0,63	4,29	0,090		Algorithm converged.	-0,085	0,264	1,457		Algorithm converged.	0,700	3,033	0,3142		0,686		Algorithm converged.	0,330	1,429
		Unevaluable/Unknown/Missing	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
	Type of surgery for primary tumor	Breast conserving surgery	23	1,3	5	21,7	33	1,8	11	33,3	0,56		Algorithm converged.	0,16	1,89	-0,116		Algorithm converged.	-0,349	0,117	0,652		Algorithm converged.	0,262	1,626	0,3590	0,2552	1,533		Algorithm converged.	0,615	3,822
		Mastectomy	50	2,8	13	26,0	44	2,4	9	20,5	1,37		Algorithm converged.	0,52	3,60	0,055		Algorithm converged.	-0,115	0,226	1,271		Algorithm converged.	0,602	2,683	0,5291		0,787		Algorithm converged.	0,373	1,661
	Tumor size	0 - < 2 cm	24	1,3	6	25,0	25	1,4	6	24,0	1,06		Algorithm converged.	0,29	3,88	0,010		Algorithm converged.	-0,231	0,251	1,042		Algorithm converged.	0,390	2,784	0,9351	-	0,960		Algorithm converged.	0,359	2,566
		>= 2 - < 5 cm	42	2,3	12	28,6	47	2,6	14	29,8	0,94		Algorithm converged.	0,38	2,36	-0,012		Algorithm converged.	-0,201	0,177	0,959		Algorithm converged.	0,501	1,836	0,8999		1,043		Algorithm converged.	0,545	1,995
		>= 5 cm	7	0,4	0	0,0	5	0,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	56	3,1	13	23,2	58	3,2	15	25,9	0,87		Algorithm converged.	0,37	2,04	-0,026		Algorithm converged.	-0,184	0,131	0,898		Algorithm converged.	0,471	1,712	0,7430	0,7280	1,114		Algorithm converged.	0,584	2,125
		No	17	0,9	5	29,4	19	1,0	5	26,3	1,17		Algorithm converged.	0,27	5,02	0,031		Algorithm converged.	-0,262	0,324	1,118		Algorithm converged.	0,390	3,203	0,8360		0,895		Algorithm converged.	0,312	2,564
	Race	White	35	1,9	8	22,9	39	2,1	12	30,8	0,67		Algorithm converged.	0,24	1,89	-0,079		Algorithm converged.	-0,280	0,122	0,743		Algorithm converged.	0,344	1,604	0,4489	-	1,346		Algorithm converged.	0,624	2,906
		Black	2	0,1	1	50,0	2	0,1	1	50,0	1,00		Algorithm converged.	0,02	50,40	0,000		Algorithm converged.	-0,980	0,980	1,000		Algorithm converged.	0,141	7,099	1,0000		1,000		Algorithm converged.	0,141	7,099
		Asian	33	1,8	9	27,3	33	1,8	5	15,2	2,10		Algorithm converged.	0,62	7,12	0,121		Algorithm converged.	-0,074	0,316	1,800		Algorithm converged.	0,675	4,801	0,2402		0,556		Algorithm converged.	0,208	1,482

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	3	0,2	0	0,0	3	0,2	2	66,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_SSC13_W15_SG.xls
26OCT2020 16:36

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Body Image Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1521	84,0	406	26,7	1573	86,3	469	29,8	0,86		Algorithm converged.	0,73	1,00	-0,031		Algorithm converged.	-0,063	0,000		0,895		Algorithm converged.	0,800	1,002	0,0542		1,117		Algorithm converged.	0,998	1,250
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	42	2,3	11	26,2	35	1,9	8	22,9	1,20		Algorithm converged.	0,42	3,41	0,033		Algorithm converged.	-0,159	0,226		1,146		Algorithm converged.	0,519	2,531	0,7364	0,3628	0,873		Algorithm converged.	0,395	1,928
		0 positive nodes, tumor > 1 cm	221	12,2	48	21,7	245	13,4	76	31,0	0,62		Algorithm converged.	0,41	0,94	-0,093		Algorithm converged.	-0,172	-0,014		0,700		Algorithm converged.	0,512	0,957	0,0253		1,428		Algorithm converged.	1,045	1,952
		1-3 positive nodes	761	42,0	214	28,1	781	42,8	234	30,0	0,91		Algorithm converged.	0,73	1,14	-0,018		Algorithm converged.	-0,064	0,027		0,939		Algorithm converged.	0,803	1,097	0,4263		1,065		Algorithm converged.	0,911	1,246
		>= 4 positive nodes	497	27,4	133	26,8	512	28,1	151	29,5	0,87		Algorithm converged.	0,66	1,15	-0,027		Algorithm converged.	-0,083	0,028		0,907		Algorithm converged.	0,745	1,106	0,3353		1,102		Algorithm converged.	0,904	1,343
	Adjuvant chemotherapy regimen	Anthracycline	1217	67,2	315	25,9	1260	69,1	366	29,0	0,85		Algorithm converged.	0,71	1,02	-0,032		Algorithm converged.	-0,067	0,003		0,891		Algorithm converged.	0,784	1,013	0,0783	0,8794	1,122		Algorithm converged.	0,987	1,276
		Non-anthracycline	304	16,8	91	29,9	313	17,2	103	32,9	0,87		Algorithm converged.	0,62	1,22	-0,030		Algorithm converged.	-0,103	0,043		0,910		Algorithm converged.	0,720	1,149	0,4270		1,099		Algorithm converged.	0,870	1,389
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	742	41,0	180	24,3	740	40,6	211	28,5	0,80		Algorithm converged.	0,64	1,01	-0,043		Algorithm converged.	-0,087	0,002		0,851		Algorithm converged.	0,717	1,009	0,0637	0,4061	1,175		Algorithm converged.	0,991	1,394
		Positive (ER and/or PgR positive)	779	43,0	226	29,0	833	45,7	258	31,0	0,91		Algorithm converged.	0,74	1,13	-0,020		Algorithm converged.	-0,064	0,025		0,937		Algorithm converged.	0,807	1,088	0,3911		1,068		Algorithm converged.	0,919	1,240

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	214	11,8	62	29,0	219	12,0	76	34,7	0,77		Algorithm converged.	0,51	1,15	-0,057		Algorithm converged.	-0,145	0,030	0,835		Algorithm converged.	0,633	1,102	0,2024	0,2371	1,198		Algorithm converged.	0,908	1,581
		Western Europe	648	35,8	185	28,5	666	36,5	205	30,8	0,90		Algorithm converged.	0,71	1,14	-0,022		Algorithm converged.	-0,072	0,027	0,928		Algorithm converged.	0,785	1,096	0,3764		1,078		Algorithm converged.	0,913	1,274
		Asia Pacific	460	25,4	125	27,2	484	26,5	136	28,1	0,95		Algorithm converged.	0,72	1,27	-0,009		Algorithm converged.	-0,066	0,048	0,967		Algorithm converged.	0,787	1,189	0,7508		1,034		Algorithm converged.	0,841	1,271
		Latin America	38	2,1	3	7,9	42	2,3	11	26,2	0,24		Algorithm converged.	0,06	0,95	-0,183		Algorithm converged.	-0,341	-0,025	0,301		Algorithm converged.	0,091	1,000	0,0499		3,317		Algorithm converged.	1,000	11,001
		Other	161	8,9	31	19,3	162	8,9	41	25,3	0,70		Algorithm converged.	0,42	1,19	-0,061		Algorithm converged.	-0,151	0,030	0,761		Algorithm converged.	0,504	1,149	0,1938		1,314		Algorithm converged.	0,870	1,985
	Protocol version	Protocol A	1037	57,3	253	24,4	1079	59,2	318	29,5	0,77		Algorithm converged.	0,64	0,94	-0,051		Algorithm converged.	-0,088	-0,013	0,828		Algorithm converged.	0,719	0,954	0,0088	0,0624	1,208		Algorithm converged.	1,049	1,391
		Protocol amendment B	484	26,7	153	31,6	494	27,1	151	30,6	1,05		Algorithm converged.	0,80	1,38	0,010		Algorithm converged.	-0,048	0,068	1,034		Algorithm converged.	0,858	1,246	0,7241		0,967		Algorithm converged.	0,802	1,165
	Nodal status	0 positive nodes	263	14,5	59	22,4	280	15,4	84	30,0	0,67		Algorithm converged.	0,46	0,99	-0,076		Algorithm converged.	-0,149	-0,002	0,748		Algorithm converged.	0,561	0,997	0,0474	0,1761	1,337		Algorithm converged.	1,003	1,782
		>= 1 positive nodes	1258	69,5	347	27,6	1293	70,9	385	29,8	0,90		Algorithm converged.	0,76	1,07	-0,022		Algorithm converged.	-0,057	0,013	0,926		Algorithm converged.	0,820	1,047	0,2214		1,079		Algorithm converged.	0,955	1,220
	Menopausal status at randomization	Premenopausal	742	41,0	210	28,3	790	43,3	242	30,6	0,89		Algorithm converged.	0,72	1,11	-0,023		Algorithm converged.	-0,069	0,022	0,924		Algorithm converged.	0,791	1,079	0,3179	0,5899	1,082		Algorithm converged.	0,927	1,264
		Postmenopausal	775	42,8	196	25,3	776	42,6	226	29,1	0,82		Algorithm converged.	0,66	1,03	-0,038		Algorithm converged.	-0,083	0,006	0,868		Algorithm converged.	0,737	1,022	0,0904		1,152		Algorithm converged.	0,978	1,356

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	7	0,4	1	14,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1344	74,2	354	26,3	1401	76,9	423	30,2	0,83		Algorithm converged.	0,70	0,98	-0,039		Algorithm converged.	-0,072	-0,005	0,872		Algorithm converged.	0,774	0,983	0,0254	0,2054	1,146		Algorithm converged.	1,017	1,292
		>= 65	177	9,8	52	29,4	172	9,4	46	26,7	1,14		Algorithm converged.	0,71	1,82	0,026		Algorithm converged.	-0,068	0,121	1,099		Algorithm converged.	0,784	1,538	0,5844		0,910		Algorithm converged.	0,650	1,275
	Histological grade	Grade 1	27	1,5	12	44,4	22	1,2	9	40,9	1,16		Algorithm converged.	0,37	3,61	0,035		Algorithm converged.	-0,243	0,313	1,086		Algorithm converged.	0,564	2,093	0,8043	0,7767	0,920		Algorithm converged.	0,478	1,773
		Grade 2	471	26,0	123	26,1	483	26,5	140	29,0	0,87		Algorithm converged.	0,65	1,15	-0,029		Algorithm converged.	-0,085	0,028	0,901		Algorithm converged.	0,733	1,107	0,3217		1,110		Algorithm converged.	0,903	1,364
		Grade 3	964	53,2	253	26,2	1009	55,3	306	30,3	0,82		Algorithm converged.	0,67	0,99	-0,041		Algorithm converged.	-0,081	-0,001	0,865		Algorithm converged.	0,751	0,997	0,0448		1,156		Algorithm converged.	1,003	1,331
		Unevaluable/Unknown/Missing	59	3,3	18	30,5	59	3,2	14	23,7	1,41		Algorithm converged.	0,62	3,19	0,068		Algorithm converged.	-0,092	0,228	1,286		Algorithm converged.	0,707	2,338	0,4101		0,778		Algorithm converged.	0,428	1,414
	Type of surgery for primary tumor	Breast conserving surgery	600	33,1	157	26,2	588	32,3	190	32,3	0,74		Algorithm converged.	0,58	0,95	-0,061		Algorithm converged.	-0,113	-0,010	0,810		Algorithm converged.	0,678	0,968	0,0203	0,1633	1,235		Algorithm converged.	1,033	1,476
		Mastectomy	921	50,9	249	27,0	984	54,0	279	28,4	0,94		Algorithm converged.	0,77	1,14	-0,013		Algorithm converged.	-0,053	0,027	0,954		Algorithm converged.	0,825	1,103	0,5210		1,049		Algorithm converged.	0,907	1,213
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	561	31,0	150	26,7	574	31,5	168	29,3	0,88		Algorithm converged.	0,68	1,14	-0,025		Algorithm converged.	-0,078	0,027	0,914		Algorithm converged.	0,758	1,101	0,3431	0,7176	1,095		Algorithm converged.	0,908	1,320

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	838	46,3	226	27,0	849	46,6	252	29,7	0,87		Algorithm converged.	0,71	1,08	-0,027		Algorithm converged.	-0,070	0,016	0,909		Algorithm converged.	0,780	1,058	0,2168		1,101		Algorithm converged.	0,945	1,281
		>= 5 cm	120	6,6	30	25,0	148	8,1	48	32,4	0,69		Algorithm converged.	0,41	1,19	-0,074		Algorithm converged.	-0,182	0,034	0,771		Algorithm converged.	0,523	1,136	0,1879		1,297		Algorithm converged.	0,881	1,911
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1177	65,0	315	26,8	1188	65,2	353	29,7	0,86		Algorithm converged.	0,72	1,03	-0,030		Algorithm converged.	-0,066	0,007	0,901		Algorithm converged.	0,792	1,024	0,1114	0,8507	1,110		Algorithm converged.	0,976	1,263
		No	344	19,0	91	26,5	385	21,1	116	30,1	0,83		Algorithm converged.	0,60	1,15	-0,037		Algorithm converged.	-0,102	0,029	0,878		Algorithm converged.	0,696	1,108	0,2732		1,139		Algorithm converged.	0,902	1,438
	Race	White	1000	55,2	274	27,4	1045	57,3	321	30,7	0,85		Algorithm converged.	0,70	1,03	-0,033		Algorithm converged.	-0,073	0,006	0,892		Algorithm converged.	0,779	1,022	0,0993	0,7041	1,121		Algorithm converged.	0,979	1,284
		Black	21	1,2	8	38,1	26	1,4	9	34,6	1,16		Algorithm converged.	0,35	3,84	0,035		Algorithm converged.	-0,242	0,312	1,101		Algorithm converged.	0,515	2,351	0,8047		0,909		Algorithm converged.	0,425	1,941
		Asian	449	24,8	116	25,8	454	24,9	127	28,0	0,90		Algorithm converged.	0,67	1,20	-0,021		Algorithm converged.	-0,079	0,036	0,924		Algorithm converged.	0,745	1,145	0,4691		1,083		Algorithm converged.	0,873	1,343
		Other	47	2,6	7	14,9	47	2,6	12	25,5	0,51		Algorithm converged.	0,18	1,44	-0,106		Algorithm converged.	-0,267	0,055	0,583		Algorithm converged.	0,252	1,351	0,2085		1,714		Algorithm converged.	0,740	3,971

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	4	0,2	1	25,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
FU MONTH 36	All	n/a	1342	74,1	271	20,2	1304	71,5	298	22,9	0,85		Algorithm converged.	0,71	1,03	-0,027		Algorithm converged.	-0,058	0,005	0,884		Algorithm converged.	0,764	1,022	0,0963		1,132		Algorithm converged.	0,978	1,309
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	42	2,3	10	23,8	35	1,9	4	11,4	2,42		Algorithm converged.	0,69	8,54	0,124		Algorithm converged.	-0,043	0,290	2,083		Algorithm converged.	0,715	6,069	0,1785	0,1352	0,480		Algorithm converged.	0,165	1,398
		0 positive nodes, tumor > 1 cm	208	11,5	32	15,4	218	12,0	51	23,4	0,60		Algorithm converged.	0,36	0,97	-0,080		Algorithm converged.	-0,155	-0,006	0,658		Algorithm converged.	0,441	0,980	0,0396		1,521		Algorithm converged.	1,020	2,266
		1-3 positive nodes	686	37,9	142	20,7	643	35,3	140	21,8	0,94		Algorithm converged.	0,72	1,22	-0,011		Algorithm converged.	-0,055	0,033	0,951		Algorithm converged.	0,773	1,170	0,6325		1,052		Algorithm converged.	0,855	1,294
		>= 4 positive nodes	406	22,4	87	21,4	408	22,4	103	25,2	0,81		Algorithm converged.	0,58	1,12	-0,038		Algorithm converged.	-0,096	0,020	0,849		Algorithm converged.	0,661	1,090	0,1991		1,178		Algorithm converged.	0,917	1,513
	Adjuvant chemotherapy regimen	Anthracycline	1070	59,1	218	20,4	1047	57,4	232	22,2	0,90		Algorithm converged.	0,73	1,11	-0,018		Algorithm converged.	-0,053	0,017	0,919		Algorithm converged.	0,780	1,083	0,3158	0,2922	1,088		Algorithm converged.	0,923	1,282
		Non-anthracycline	272	15,0	53	19,5	257	14,1	66	25,7	0,70		Algorithm converged.	0,46	1,06	-0,062		Algorithm converged.	-0,133	0,009	0,759		Algorithm converged.	0,552	1,044	0,0896		1,318		Algorithm converged.	0,958	1,813
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	655	36,2	123	18,8	633	34,7	133	21,0	0,87		Algorithm converged.	0,66	1,14	-0,022		Algorithm converged.	-0,066	0,021	0,894		Algorithm converged.	0,718	1,113	0,3159	0,8939	1,119		Algorithm converged.	0,898	1,394

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	687	37,9	148	21,5	671	36,8	165	24,6	0,84		Algorithm converged.	0,65	1,08	-0,030		Algorithm converged.	-0,075	0,014	0,876		Algorithm converged.	0,721	1,064	0,1830		1,141		Algorithm converged.	0,939	1,387
	Geographical region II	USA/Canada	177	9,8	44	24,9	149	8,2	37	24,8	1,00		Algorithm converged.	0,60	1,66	0,000		Algorithm converged.	-0,094	0,094	1,001		Algorithm converged.	0,685	1,462	0,9956	-	0,999		Algorithm converged.	0,684	1,459
		Western Europe	572	31,6	122	21,3	562	30,8	131	23,3	0,89		Algorithm converged.	0,67	1,18	-0,020		Algorithm converged.	-0,068	0,029	0,915		Algorithm converged.	0,736	1,137	0,4233		1,093		Algorithm converged.	0,879	1,358
		Asia Pacific	414	22,9	82	19,8	427	23,4	98	23,0	0,83		Algorithm converged.	0,60	1,15	-0,031		Algorithm converged.	-0,087	0,024	0,863		Algorithm converged.	0,665	1,120	0,2673		1,159		Algorithm converged.	0,893	1,503
		Latin America	34	1,9	1	2,9	36	2,0	6	16,7	0,15		Algorithm converged.	0,02	1,33	-0,137		Algorithm converged.	-0,272	-0,003	0,176		Algorithm converged.	0,022	1,391	0,0996		5,667		Algorithm converged.	0,719	44,659
		Other	145	8,0	22	15,2	130	7,1	26	20,0	0,72		Algorithm converged.	0,38	1,34	-0,048		Algorithm converged.	-0,138	0,042	0,759		Algorithm converged.	0,453	1,271	0,2941		1,318		Algorithm converged.	0,787	2,208
	Protocol version	Protocol A	941	52,0	177	18,8	902	49,5	201	22,3	0,81		Algorithm converged.	0,64	1,01	-0,035		Algorithm converged.	-0,072	0,002	0,844		Algorithm converged.	0,705	1,011	0,0653	0,3685	1,185		Algorithm converged.	0,989	1,419
		Protocol amendment B	401	22,1	94	23,4	402	22,1	97	24,1	0,96		Algorithm converged.	0,70	1,33	-0,007		Algorithm converged.	-0,066	0,052	0,971		Algorithm converged.	0,758	1,244	0,8189		1,029		Algorithm converged.	0,804	1,319
	Nodal status	0 positive nodes	250	13,8	42	16,8	253	13,9	55	21,7	0,73		Algorithm converged.	0,47	1,14	-0,049		Algorithm converged.	-0,118	0,019	0,773		Algorithm converged.	0,538	1,109	0,1624	0,4256	1,294		Algorithm converged.	0,901	1,858
		>= 1 positive nodes	1092	60,3	229	21,0	1051	57,7	243	23,1	0,88		Algorithm converged.	0,72	1,08	-0,022		Algorithm converged.	-0,057	0,014	0,907		Algorithm converged.	0,773	1,064	0,2301		1,103		Algorithm converged.	0,940	1,293
	Menopausal status at randomization	Premenopausal	654	36,1	142	21,7	651	35,7	150	23,0	0,93		Algorithm converged.	0,71	1,20	-0,013		Algorithm converged.	-0,059	0,032	0,942		Algorithm converged.	0,770	1,154	0,5647	0,4061	1,061		Algorithm converged.	0,867	1,299
		Postmenopausal	684	37,8	129	18,9	649	35,6	147	22,7	0,79		Algorithm converged.	0,61	1,04	-0,038		Algorithm converged.	-0,081	0,006	0,833		Algorithm converged.	0,674	1,028	0,0884		1,201		Algorithm converged.	0,973	1,483

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	4	0,2	0	0,0	4	0,2	1	25,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Age II	< 65	1193	65,9	239	20,0	1166	64,0	262	22,5	0,86		Algorithm converged.	0,71	1,05	-0,024		Algorithm converged.	-0,057	0,009	0,892		Algorithm converged.	0,763	1,042	0,1483	0,7249	1,122		Algorithm converged.	0,960	1,310
		>= 65	149	8,2	32	21,5	138	7,6	36	26,1	0,77		Algorithm converged.	0,45	1,34	-0,046		Algorithm converged.	-0,145	0,052	0,823		Algorithm converged.	0,543	1,248	0,3596		1,215		Algorithm converged.	0,801	1,841
	Histological grade	Grade 1	26	1,4	4	15,4	20	1,1	4	20,0	0,73		Algorithm converged.	0,16	3,35	-0,046		Algorithm converged.	-0,270	0,177	0,769		Algorithm converged.	0,219	2,705	0,6826	-	1,300		Algorithm converged.	0,370	4,571
		Grade 2	422	23,3	76	18,0	402	22,1	89	22,1	0,77		Algorithm converged.	0,55	1,09	-0,041		Algorithm converged.	-0,096	0,013	0,813		Algorithm converged.	0,619	1,070	0,1397		1,229		Algorithm converged.	0,935	1,617
		Grade 3	845	46,7	177	20,9	832	45,6	197	23,7	0,85		Algorithm converged.	0,68	1,08	-0,027		Algorithm converged.	-0,067	0,013	0,885		Algorithm converged.	0,740	1,058	0,1796		1,130		Algorithm converged.	0,945	1,352
		Unevaluable/Unknown/Missing	49	2,7	14	28,6	50	2,7	8	16,0	2,10		Algorithm converged.	0,79	5,58	0,126		Algorithm converged.	-0,037	0,288	1,786		Algorithm converged.	0,823	3,873	0,1421		0,560		Algorithm converged.	0,258	1,215
	Type of surgery for primary tumor	Breast conserving surgery	536	29,6	102	19,0	510	28,0	111	21,8	0,84		Algorithm converged.	0,63	1,14	-0,027		Algorithm converged.	-0,076	0,022	0,874		Algorithm converged.	0,688	1,111	0,2727	0,9067	1,144		Algorithm converged.	0,900	1,454
		Mastectomy	806	44,5	169	21,0	794	43,6	187	23,6	0,86		Algorithm converged.	0,68	1,09	-0,026		Algorithm converged.	-0,067	0,015	0,890		Algorithm converged.	0,741	1,070	0,2145		1,123		Algorithm converged.	0,935	1,349
	Tumor size	0 - < 2 cm	508	28,1	96	18,9	480	26,3	97	20,2	0,92		Algorithm converged.	0,67	1,26	-0,013		Algorithm converged.	-0,063	0,036	0,935		Algorithm converged.	0,726	1,204	0,6035	0,7942	1,069		Algorithm converged.	0,830	1,377

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 2 - < 5 cm	736	40,6	151	20,5	710	38,9	171	24,1	0,81		Algorithm converged.	0,63	1,04	-0,036		Algorithm converged.	-0,079	0,007	0,852		Algorithm converged.	0,702	1,033	0,1036		1,174		Algorithm converged.	0,968	1,424
		>= 5 cm	96	5,3	24	25,0	112	6,1	29	25,9	0,95		Algorithm converged.	0,51	1,78	-0,009		Algorithm converged.	-0,128	0,110	0,966		Algorithm converged.	0,605	1,540	0,8829		1,036		Algorithm converged.	0,649	1,652
		Missing	2	0,1	0	0,0	2	0,1	1	50,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,000		Algorithm converged.	0,000	NE	1,0000		>999		Algorithm converged.	0,000	NE
	Loco-regional radiotherapy	Yes	1026	56,7	209	20,4	992	54,4	229	23,1	0,85		Algorithm converged.	0,69	1,05	-0,027		Algorithm converged.	-0,063	0,009	0,882		Algorithm converged.	0,747	1,042	0,1396	0,9758	1,133		Algorithm converged.	0,960	1,338
		No	316	17,4	62	19,6	312	17,1	69	22,1	0,86		Algorithm converged.	0,58	1,26	-0,025		Algorithm converged.	-0,088	0,039	0,887		Algorithm converged.	0,654	1,204	0,4421		1,127		Algorithm converged.	0,831	1,529
	Race	White	877	48,4	185	21,1	859	47,1	194	22,6	0,92		Algorithm converged.	0,73	1,15	-0,015		Algorithm converged.	-0,054	0,024	0,934		Algorithm converged.	0,782	1,116	0,4526	-	1,071		Algorithm converged.	0,896	1,279
		Black	18	1,0	3	16,7	18	1,0	9	50,0	0,20		Algorithm converged.	0,04	0,94	-0,333		Algorithm converged.	-0,621	-0,045	0,333		Algorithm converged.	0,108	1,034	0,0571		3,000		Algorithm converged.	0,968	9,302
		Asian	399	22,0	80	20,1	393	21,6	90	22,9	0,84		Algorithm converged.	0,60	1,19	-0,029		Algorithm converged.	-0,086	0,029	0,876		Algorithm converged.	0,670	1,143	0,3292		1,142		Algorithm converged.	0,875	1,492
		Other	43	2,4	3	7,0	33	1,8	5	15,2	0,42		Algorithm converged.	0,09	1,90	-0,082		Algorithm converged.	-0,226	0,062	0,460		Algorithm converged.	0,118	1,790	0,2629		2,172		Algorithm converged.	0,559	8,441
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC06_W15_SG.xls
26OCT2020 15:47

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1456	80,4	336	23,1	1509	82,8	358	23,7	0,96		Algorithm converged.	0,81	1,14	-0,006		Algorithm converged.	-0,037	0,024		0,973		Algorithm converged.	0,854	1,108	0,6773		1,028		Algorithm converged.	0,902	1,171
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	40	2,2	11	27,5	33	1,8	8	24,2	1,19		Algorithm converged.	0,41	3,41	0,033		Algorithm converged.	-0,169	0,234		1,134		Algorithm converged.	0,517	2,488	0,7531	0,8775	0,882		Algorithm converged.	0,402	1,934
		0 positive nodes, tumor > 1 cm	208	11,5	44	21,2	234	12,8	55	23,5	0,87		Algorithm converged.	0,56	1,37	-0,024		Algorithm converged.	-0,101	0,054		0,900		Algorithm converged.	0,634	1,277	0,5548		1,111		Algorithm converged.	0,783	1,576
		1-3 positive nodes	737	40,7	170	23,1	747	41,0	182	24,4	0,93		Algorithm converged.	0,73	1,18	-0,013		Algorithm converged.	-0,056	0,030		0,947		Algorithm converged.	0,789	1,136	0,5569		1,056		Algorithm converged.	0,880	1,268
		>= 4 positive nodes	471	26,0	111	23,6	495	27,2	113	22,8	1,04		Algorithm converged.	0,77	1,41	0,007		Algorithm converged.	-0,046	0,061		1,032		Algorithm converged.	0,821	1,299	0,7857		0,969		Algorithm converged.	0,770	1,219
	Adjuvant chemotherapy regimen	Anthracycline	1167	64,4	267	22,9	1212	66,5	286	23,6	0,96		Algorithm converged.	0,79	1,16	-0,007		Algorithm converged.	-0,041	0,027		0,970		Algorithm converged.	0,838	1,122	0,6785	0,9243	1,031		Algorithm converged.	0,891	1,194
		Non-anthracycline	289	16,0	69	23,9	297	16,3	72	24,2	0,98		Algorithm converged.	0,67	1,43	-0,004		Algorithm converged.	-0,073	0,066		0,985		Algorithm converged.	0,739	1,313	0,9172		1,015		Algorithm converged.	0,761	1,354
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	703	38,8	157	22,3	710	38,9	163	23,0	0,96		Algorithm converged.	0,75	1,24	-0,006		Algorithm converged.	-0,050	0,037		0,973		Algorithm converged.	0,802	1,180	0,7790	0,9924	1,028		Algorithm converged.	0,848	1,247
		Positive (ER and/or PgR positive)	753	41,6	179	23,8	799	43,8	195	24,4	0,97		Algorithm converged.	0,77	1,22	-0,006		Algorithm converged.	-0,049	0,036		0,974		Algorithm converged.	0,816	1,162	0,7704		1,027		Algorithm converged.	0,860	1,225

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	206	11,4	48	23,3	215	11,8	60	27,9	0,78		Algorithm converged.	0,51	1,22	-0,046		Algorithm converged.	-0,129	0,037	0,835		Algorithm converged.	0,602	1,159	0,2810	0,6836	1,198		Algorithm converged.	0,863	1,662
		Western Europe	607	33,5	150	24,7	617	33,8	162	26,3	0,92		Algorithm converged.	0,71	1,19	-0,015		Algorithm converged.	-0,064	0,033	0,941		Algorithm converged.	0,777	1,140	0,5355		1,062		Algorithm converged.	0,877	1,287
		Asia Pacific	458	25,3	93	20,3	483	26,5	96	19,9	1,03		Algorithm converged.	0,75	1,41	0,004		Algorithm converged.	-0,047	0,056	1,022		Algorithm converged.	0,792	1,318	0,8693		0,979		Algorithm converged.	0,759	1,263
		Latin America	33	1,8	9	27,3	38	2,1	10	26,3	1,05		Algorithm converged.	0,37	3,01	0,010		Algorithm converged.	-0,197	0,216	1,036		Algorithm converged.	0,480	2,239	0,9276		0,965		Algorithm converged.	0,447	2,085
		Other	152	8,4	36	23,7	156	8,6	30	19,2	1,30		Algorithm converged.	0,75	2,25	0,045		Algorithm converged.	-0,047	0,136	1,232		Algorithm converged.	0,801	1,893	0,3423		0,812		Algorithm converged.	0,528	1,248
	Protocol version	Protocol A	990	54,7	230	23,2	1036	56,8	248	23,9	0,96		Algorithm converged.	0,78	1,18	-0,007		Algorithm converged.	-0,044	0,030	0,971		Algorithm converged.	0,830	1,135	0,7084	0,9567	1,030		Algorithm converged.	0,881	1,205
		Protocol amendment B	466	25,7	106	22,7	473	25,9	110	23,3	0,97		Algorithm converged.	0,72	1,32	-0,005		Algorithm converged.	-0,059	0,049	0,978		Algorithm converged.	0,774	1,236	0,8530		1,022		Algorithm converged.	0,809	1,292
	Nodal status	0 positive nodes	248	13,7	55	22,2	267	14,6	63	23,6	0,92		Algorithm converged.	0,61	1,39	-0,014		Algorithm converged.	-0,087	0,058	0,940		Algorithm converged.	0,684	1,291	0,7022	0,8170	1,064		Algorithm converged.	0,774	1,462
		>= 1 positive nodes	1208	66,7	281	23,3	1242	68,1	295	23,8	0,97		Algorithm converged.	0,81	1,17	-0,005		Algorithm converged.	-0,038	0,029	0,979		Algorithm converged.	0,849	1,130	0,7748		1,021		Algorithm converged.	0,885	1,178
	Menopausal status at randomization	Premenopausal	734	40,5	203	27,7	778	42,7	226	29,0	0,93		Algorithm converged.	0,75	1,17	-0,014		Algorithm converged.	-0,059	0,032	0,952		Algorithm converged.	0,811	1,118	0,5486	0,4963	1,050		Algorithm converged.	0,895	1,233
		Postmenopausal	718	39,6	132	18,4	723	39,7	127	17,6	1,06		Algorithm converged.	0,81	1,38	0,008		Algorithm converged.	-0,031	0,048	1,047		Algorithm converged.	0,839	1,305	0,6857		0,955		Algorithm converged.	0,766	1,191
		Unknown/Missing	4	0,2	1	25,0	8	0,4	5	62,5	0,20		Algorithm converged.	0,01	2,91	-0,375		Algorithm converged.	-0,916	0,166	0,400		Algorithm converged.	0,067	2,372	0,3131		2,500		Algorithm converged.	0,422	14,828
	Age II	< 65	1302	71,9	312	24,0	1359	74,5	343	25,2	0,93		Algorithm converged.	0,78	1,11	-0,013		Algorithm converged.	-0,045	0,020	0,949		Algorithm converged.	0,831	1,085	0,4451	0,1108	1,053		Algorithm converged.	0,922	1,203
		>= 65	154	8,5	24	15,6	150	8,2	15	10,0	1,66		Algorithm converged.	0,83	3,31	0,056		Algorithm converged.	-0,019	0,131	1,558		Algorithm converged.	0,851	2,853	0,1504		0,642		Algorithm converged.	0,351	1,175

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	26	1,4	3	11,5	21	1,2	8	38,1	0,21		Algorithm converged.	0,05	0,94	-0,266		Algorithm converged.	-0,507	-0,024	0,303		Algorithm converged.	0,092	1,001	0,0503	0,0512	3,302		Algorithm converged.	0,999	10,916
		Grade 2	451	24,9	90	20,0	469	25,7	107	22,8	0,84		Algorithm converged.	0,61	1,16	-0,029		Algorithm converged.	-0,082	0,024	0,875		Algorithm converged.	0,682	1,122	0,2915		1,143		Algorithm converged.	0,891	1,466
		Grade 3	920	50,8	231	25,1	963	52,8	231	24,0	1,06		Algorithm converged.	0,86	1,31	0,011		Algorithm converged.	-0,028	0,050	1,047		Algorithm converged.	0,893	1,226	0,5720		0,955		Algorithm converged.	0,815	1,119
		Unevaluable/Unknown/Missing	59	3,3	12	20,3	56	3,1	12	21,4	0,94		Algorithm converged.	0,38	2,30	-0,011		Algorithm converged.	-0,160	0,138	0,949		Algorithm converged.	0,466	1,934	0,8857		1,054		Algorithm converged.	0,517	2,147
	Type of surgery for primary tumor	Breast conserving surgery	566	31,3	151	26,7	564	30,9	145	25,7	1,05		Algorithm converged.	0,81	1,37	0,010		Algorithm converged.	-0,042	0,061	1,038		Algorithm converged.	0,853	1,262	0,7110	0,3776	0,964		Algorithm converged.	0,792	1,172
		Mastectomy	890	49,1	185	20,8	945	51,8	213	22,5	0,90		Algorithm converged.	0,72	1,13	-0,018		Algorithm converged.	-0,055	0,020	0,922		Algorithm converged.	0,775	1,098	0,3628		1,084		Algorithm converged.	0,911	1,291
	Tumor size	0 - < 2 cm	532	29,4	129	24,2	553	30,3	140	25,3	0,94		Algorithm converged.	0,72	1,24	-0,011		Algorithm converged.	-0,062	0,041	0,958		Algorithm converged.	0,778	1,179	0,6838	0,9773	1,044		Algorithm converged.	0,848	1,285
		>= 2 - < 5 cm	807	44,6	184	22,8	816	44,8	189	23,2	0,98		Algorithm converged.	0,78	1,23	-0,004		Algorithm converged.	-0,045	0,037	0,984		Algorithm converged.	0,824	1,176	0,8627		1,016		Algorithm converged.	0,850	1,214
		>= 5 cm	115	6,4	23	20,0	138	7,6	29	21,0	0,94		Algorithm converged.	0,51	1,74	-0,010		Algorithm converged.	-0,110	0,090	0,952		Algorithm converged.	0,584	1,551	0,8425		1,051		Algorithm converged.	0,645	1,712
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1123	62,0	274	24,4	1134	62,2	272	24,0	1,02		Algorithm converged.	0,84	1,24	0,004		Algorithm converged.	-0,031	0,039	1,017		Algorithm converged.	0,879	1,177	0,8188	0,1728	0,983		Algorithm converged.	0,849	1,138
		No	333	18,4	62	18,6	375	20,6	86	22,9	0,77		Algorithm converged.	0,53	1,11	-0,043		Algorithm converged.	-0,103	0,017	0,812		Algorithm converged.	0,607	1,086	0,1608		1,232		Algorithm converged.	0,920	1,648
	Race	White	942	52,0	229	24,3	987	54,1	248	25,1	0,96		Algorithm converged.	0,78	1,18	-0,008		Algorithm converged.	-0,047	0,030	0,967		Algorithm converged.	0,828	1,131	0,6778	-	1,034		Algorithm converged.	0,884	1,208
		Black	21	1,2	4	19,0	26	1,4	5	19,2	0,99		Algorithm converged.	0,23	4,26	-0,002		Algorithm converged.	-0,228	0,224	0,990		Algorithm converged.	0,304	3,231	0,9873		1,010		Algorithm converged.	0,310	3,293

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asian	446	24,6	90	20,2	453	24,8	91	20,1	1,01		Algorithm converged.	0,73	1,39	0,001		Algorithm converged.	-0,052	0,053	1,005		Algorithm converged.	0,774	1,303	0,9728		0,995		Algorithm converged.	0,767	1,292
		Other	43	2,4	13	30,2	42	2,3	14	33,3	0,87		Algorithm converged.	0,35	2,16	-0,031		Algorithm converged.	-0,229	0,167	0,907		Algorithm converged.	0,486	1,692	0,7590		1,103		Algorithm converged.	0,591	2,057
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1279	70,6	258	20,2	1251	68,6	269	21,5	0,92		Algorithm converged.	0,76	1,12	-0,013		Algorithm converged.	-0,045	0,018	0,938		Algorithm converged.	0,806	1,092	0,4100		1,066		Algorithm converged.	0,916	1,241
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	39	2,2	4	10,3	32	1,8	9	28,1	0,29		Algorithm converged.	0,08	1,06	-0,179		Algorithm converged.	-0,361	0,004	0,365		Algorithm converged.	0,124	1,075	0,0674	0,2715	2,742		Algorithm converged.	0,930	8,083
		0 positive nodes, tumor > 1 cm	195	10,8	36	18,5	210	11,5	35	16,7	1,13		Algorithm converged.	0,68	1,89	0,018		Algorithm converged.	-0,056	0,092	1,108		Algorithm converged.	0,726	1,690	0,6351		0,903		Algorithm converged.	0,592	1,377
		1-3 positive nodes	661	36,5	139	21,0	610	33,5	138	22,6	0,91		Algorithm converged.	0,70	1,19	-0,016		Algorithm converged.	-0,061	0,030	0,930		Algorithm converged.	0,755	1,145	0,4916		1,076		Algorithm converged.	0,874	1,325
		>= 4 positive nodes	384	21,2	79	20,6	399	21,9	87	21,8	0,93		Algorithm converged.	0,66	1,31	-0,012		Algorithm converged.	-0,070	0,045	0,944		Algorithm converged.	0,720	1,237	0,6735		1,060		Algorithm converged.	0,809	1,389
	Adjuvant chemotherapy regimen	Anthracycline	1021	56,4	203	19,9	1007	55,2	211	21,0	0,94		Algorithm converged.	0,75	1,16	-0,011		Algorithm converged.	-0,046	0,024	0,949		Algorithm converged.	0,799	1,127	0,5498	0,7633	1,054		Algorithm converged.	0,887	1,252
		Non-anthracycline	258	14,2	55	21,3	244	13,4	58	23,8	0,87		Algorithm converged.	0,57	1,32	-0,025		Algorithm converged.	-0,098	0,049	0,897		Algorithm converged.	0,648	1,241	0,5110		1,115		Algorithm converged.	0,806	1,543
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	624	34,5	111	17,8	605	33,2	122	20,2	0,86		Algorithm converged.	0,64	1,14	-0,024		Algorithm converged.	-0,068	0,020	0,882		Algorithm converged.	0,700	1,112	0,2883	0,4756	1,134		Algorithm converged.	0,899	1,429
		Positive (ER and/or PgR positive)	655	36,2	147	22,4	646	35,4	147	22,8	0,98		Algorithm converged.	0,76	1,27	-0,003		Algorithm converged.	-0,049	0,042	0,986		Algorithm converged.	0,807	1,206	0,8927		1,014		Algorithm converged.	0,829	1,240

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	174	9,6	41	23,6	148	8,1	34	23,0	1,03		Algorithm converged.	0,62	1,74	0,006		Algorithm converged.	-0,087	0,098	1,026		Algorithm converged.	0,689	1,528	0,9007	0,6702	0,975		Algorithm converged.	0,655	1,452
		Western Europe	528	29,2	103	19,5	518	28,4	123	23,7	0,78		Algorithm converged.	0,58	1,05	-0,042		Algorithm converged.	-0,092	0,007	0,822		Algorithm converged.	0,651	1,036	0,0968		1,217		Algorithm converged.	0,965	1,535
		Asia Pacific	411	22,7	83	20,2	424	23,3	83	19,6	1,04		Algorithm converged.	0,74	1,46	0,006		Algorithm converged.	-0,048	0,060	1,032		Algorithm converged.	0,786	1,355	0,8227		0,969		Algorithm converged.	0,738	1,273
		Latin America	30	1,7	7	23,3	34	1,9	9	26,5	0,85		Algorithm converged.	0,27	2,64	-0,031		Algorithm converged.	-0,243	0,181	0,881		Algorithm converged.	0,374	2,077	0,7730		1,134		Algorithm converged.	0,481	2,673
		Other	136	7,5	24	17,6	127	7,0	20	15,7	1,15		Algorithm converged.	0,60	2,20	0,019		Algorithm converged.	-0,071	0,109	1,121		Algorithm converged.	0,652	1,927	0,6805		0,892		Algorithm converged.	0,519	1,534
	Protocol version	Protocol A	897	49,5	179	20,0	867	47,6	194	22,4	0,86		Algorithm converged.	0,69	1,09	-0,024		Algorithm converged.	-0,062	0,014	0,892		Algorithm converged.	0,745	1,068	0,2136	0,3153	1,121		Algorithm converged.	0,936	1,343
		Protocol amendment B	382	21,1	79	20,7	384	21,1	75	19,5	1,07		Algorithm converged.	0,75	1,53	0,011		Algorithm converged.	-0,045	0,068	1,059		Algorithm converged.	0,798	1,404	0,6915		0,944		Algorithm converged.	0,712	1,253
	Nodal status	0 positive nodes	234	12,9	40	17,1	242	13,3	44	18,2	0,93		Algorithm converged.	0,58	1,49	-0,011		Algorithm converged.	-0,079	0,058	0,940		Algorithm converged.	0,637	1,387	0,7557	0,9816	1,064		Algorithm converged.	0,721	1,569
		>= 1 positive nodes	1045	57,7	218	20,9	1009	55,3	225	22,3	0,92		Algorithm converged.	0,74	1,13	-0,014		Algorithm converged.	-0,050	0,021	0,936		Algorithm converged.	0,793	1,103	0,4283		1,069		Algorithm converged.	0,906	1,261
	Menopausal status at randomization	Premenopausal	643	35,5	159	24,7	641	35,2	159	24,8	1,00		Algorithm converged.	0,77	1,28	-0,001		Algorithm converged.	-0,048	0,046	0,997		Algorithm converged.	0,824	1,206	0,9745	0,3318	1,003		Algorithm converged.	0,829	1,214
		Postmenopausal	632	34,9	97	15,3	606	33,2	109	18,0	0,83		Algorithm converged.	0,61	1,12	-0,026		Algorithm converged.	-0,068	0,015	0,853		Algorithm converged.	0,665	1,095	0,2133		1,172		Algorithm converged.	0,913	1,505
		Unknown/Missing	4	0,2	2	50,0	4	0,2	1	25,0	3,00		Algorithm converged.	0,15	59,89	0,250		Algorithm converged.	-0,398	0,898	2,000		Algorithm converged.	0,282	14,198	0,4882		0,500		Algorithm converged.	0,070	3,550
	Age II	< 65	1152	63,6	241	20,9	1130	62,0	251	22,2	0,93		Algorithm converged.	0,76	1,13	-0,013		Algorithm converged.	-0,047	0,021	0,942		Algorithm converged.	0,805	1,101	0,4530	0,8878	1,062		Algorithm converged.	0,908	1,242
		>= 65	127	7,0	17	13,4	121	6,6	18	14,9	0,88		Algorithm converged.	0,43	1,81	-0,015		Algorithm converged.	-0,102	0,072	0,900		Algorithm converged.	0,487	1,663	0,7363		1,111		Algorithm converged.	0,601	2,054

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	25	1,4	9	36,0	19	1,0	9	47,4	0,63		Algorithm converged.	0,19	2,11	-0,114		Algorithm converged.	-0,407	0,179	0,760		Algorithm converged.	0,375	1,539	0,4458	0,7891	1,316		Algorithm converged.	0,650	2,664
		Grade 2	409	22,6	76	18,6	391	21,4	83	21,2	0,85		Algorithm converged.	0,60	1,20	-0,026		Algorithm converged.	-0,082	0,029	0,875		Algorithm converged.	0,663	1,157	0,3490		1,142		Algorithm converged.	0,865	1,509
		Grade 3	797	44,0	161	20,2	791	43,4	169	21,4	0,93		Algorithm converged.	0,73	1,19	-0,012		Algorithm converged.	-0,052	0,028	0,945		Algorithm converged.	0,780	1,146	0,5675		1,058		Algorithm converged.	0,873	1,282
		Unevaluable/Unknown/Missing	48	2,7	12	25,0	50	2,7	8	16,0	1,75		Algorithm converged.	0,64	4,75	0,090		Algorithm converged.	-0,069	0,249	1,562		Algorithm converged.	0,701	3,485	0,2755		0,640		Algorithm converged.	0,287	1,427
	Type of surgery for primary tumor	Breast conserving surgery	498	27,5	102	20,5	480	26,3	114	23,8	0,83		Algorithm converged.	0,61	1,12	-0,033		Algorithm converged.	-0,085	0,019	0,862		Algorithm converged.	0,681	1,092	0,2187	0,3681	1,160		Algorithm converged.	0,916	1,468
		Mastectomy	781	43,1	156	20,0	771	42,3	155	20,1	0,99		Algorithm converged.	0,77	1,27	-0,001		Algorithm converged.	-0,041	0,039	0,994		Algorithm converged.	0,814	1,212	0,9492		1,006		Algorithm converged.	0,825	1,228
	Tumor size	0 - < 2 cm	479	26,4	95	19,8	457	25,1	103	22,5	0,85		Algorithm converged.	0,62	1,16	-0,027		Algorithm converged.	-0,079	0,025	0,880		Algorithm converged.	0,687	1,127	0,3114	0,6182	1,136		Algorithm converged.	0,887	1,456
		>= 2 - < 5 cm	705	38,9	141	20,0	687	37,7	146	21,3	0,93		Algorithm converged.	0,71	1,20	-0,013		Algorithm converged.	-0,055	0,030	0,941		Algorithm converged.	0,766	1,157	0,5639		1,063		Algorithm converged.	0,865	1,306
		>= 5 cm	93	5,1	21	22,6	105	5,8	20	19,0	1,24		Algorithm converged.	0,62	2,47	0,035		Algorithm converged.	-0,078	0,149	1,185		Algorithm converged.	0,687	2,045	0,5407		0,844		Algorithm converged.	0,489	1,455
		Missing	2	0,1	1	50,0	2	0,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Loco-regional radiotherapy	Yes	974	53,8	206	21,1	948	52,0	216	22,8	0,91		Algorithm converged.	0,73	1,13	-0,016		Algorithm converged.	-0,053	0,021	0,928		Algorithm converged.	0,784	1,099	0,3868	0,8045	1,077		Algorithm converged.	0,910	1,275
		No	305	16,8	52	17,0	303	16,6	53	17,5	0,97		Algorithm converged.	0,64	1,48	-0,004		Algorithm converged.	-0,065	0,056	0,975		Algorithm converged.	0,688	1,380	0,8852		1,026		Algorithm converged.	0,724	1,453
	Race	White	819	45,2	162	19,8	812	44,5	180	22,2	0,87		Algorithm converged.	0,68	1,10	-0,024		Algorithm converged.	-0,063	0,016	0,892		Algorithm converged.	0,739	1,078	0,2368	-	1,121		Algorithm converged.	0,928	1,354
		Black	18	1,0	4	22,2	17	0,9	3	17,6	1,33		Algorithm converged.	0,25	7,08	0,046		Algorithm converged.	-0,218	0,310	1,259		Algorithm converged.	0,329	4,820	0,7364		0,794		Algorithm converged.	0,207	3,039
		Asian	397	21,9	81	20,4	390	21,4	78	20,0	1,03		Algorithm converged.	0,72	1,45	0,004		Algorithm converged.	-0,052	0,060	1,020		Algorithm converged.	0,773	1,347	0,8880		0,980		Algorithm converged.	0,743	1,294
		Other	40	2,2	10	25,0	31	1,7	8	25,8	0,96		Algorithm converged.	0,33	2,81	-0,008		Algorithm converged.	-0,212	0,196	0,969		Algorithm converged.	0,434	2,162	0,9382		1,032		Algorithm converged.	0,463	2,304
		Missing	5	0,3	1	20,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC07_W15_SG.xls
26OCT2020 15:50

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Enjoyment Iter
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	437	24,1	147	33,6	481	26,4	159	33,1	1,03		Algorithm converged.	0,78	1,35	0,006		Algorithm converged.	-0,055	0,067	1,018		Algorithm converged.	0,847	1,222	0,8517		0,983		Algorithm converged.	0,818	1,180
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	15	0,8	4	26,7	20	1,1	4	20,0	1,45		Algorithm converged.	0,30	7,09	0,067		Algorithm converged.	-0,218	0,351	1,333		Algorithm converged.	0,396	4,487	0,6422	-	0,750		Algorithm converged.	0,223	2,524
		0 positive nodes, tumor > 1 cm	60	3,3	16	26,7	61	3,3	23	37,7	0,60		Algorithm converged.	0,28	1,30	-0,110		Algorithm converged.	-0,276	0,055	0,707		Algorithm converged.	0,417	1,201	0,1996		1,414		Algorithm converged.	0,833	2,400
		1-3 positive nodes	235	13,0	85	36,2	241	13,2	84	34,9	1,06		Algorithm converged.	0,73	1,54	0,013		Algorithm converged.	-0,073	0,099	1,038		Algorithm converged.	0,815	1,322	0,7643		0,964		Algorithm converged.	0,756	1,228
		>= 4 positive nodes	127	7,0	42	33,1	159	8,7	48	30,2	1,14		Algorithm converged.	0,69	1,89	0,029		Algorithm converged.	-0,080	0,137	1,095		Algorithm converged.	0,778	1,542	0,6015		0,913		Algorithm converged.	0,648	1,285
	Adjuvant chemotherapy regimen	Anthracycline	358	19,8	115	32,1	386	21,2	127	32,9	0,97		Algorithm converged.	0,71	1,31	-0,008		Algorithm converged.	-0,075	0,060	0,976		Algorithm converged.	0,794	1,201	0,8208	0,3542	1,024		Algorithm converged.	0,832	1,260
		Non-anthracycline	79	4,4	32	40,5	95	5,2	32	33,7	1,34		Algorithm converged.	0,72	2,49	0,068		Algorithm converged.	-0,076	0,212	1,203		Algorithm converged.	0,815	1,774	0,3523		0,832		Algorithm converged.	0,564	1,227
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	192	10,6	60	31,3	207	11,4	68	32,9	0,93		Algorithm converged.	0,61	1,42	-0,016		Algorithm converged.	-0,108	0,076	0,951		Algorithm converged.	0,714	1,267	0,7324	0,5382	1,051		Algorithm converged.	0,790	1,400
		Positive (ER and/or PgR positive)	245	13,5	87	35,5	274	15,0	91	33,2	1,11		Algorithm converged.	0,77	1,59	0,023		Algorithm converged.	-0,059	0,105	1,069		Algorithm converged.	0,843	1,357	0,5817		0,935		Algorithm converged.	0,737	1,187

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk										
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	82	4,5	32	39,0	82	4,5	31	37,8	1,05		Algorithm converged.	0,56	1,98	0,012		Algorithm converged.	-0,137	0,161	1,032		Algorithm converged.	0,701	1,521	0,8725	-	0,969		Algorithm converged.	0,657	1,427
		Western Europe	232	12,8	85	36,6	267	14,6	95	35,6	1,05		Algorithm converged.	0,73	1,51	0,011		Algorithm converged.	-0,074	0,095	1,030		Algorithm converged.	0,815	1,301	0,8061		0,971		Algorithm converged.	0,769	1,227
		Asia Pacific	68	3,8	16	23,5	84	4,6	17	20,2	1,21		Algorithm converged.	0,56	2,63	0,033		Algorithm converged.	-0,100	0,165	1,163		Algorithm converged.	0,636	2,125	0,6244		0,860		Algorithm converged.	0,471	1,572
		Latin America	10	0,6	4	40,0	13	0,7	4	30,8	1,50		Algorithm converged.	0,27	8,45	0,092		Algorithm converged.	-0,302	0,486	1,300		Algorithm converged.	0,427	3,961	0,6444		0,769		Algorithm converged.	0,252	2,344
		Other	45	2,5	10	22,2	35	1,9	12	34,3	0,55		Algorithm converged.	0,20	1,47	-0,121		Algorithm converged.	-0,319	0,078	0,648		Algorithm converged.	0,318	1,323	0,2336		1,543		Algorithm converged.	0,756	3,149
	Protocol version	Protocol A	303	16,7	103	34,0	345	18,9	113	32,8	1,06		Algorithm converged.	0,76	1,47	0,012		Algorithm converged.	-0,060	0,085	1,038		Algorithm converged.	0,835	1,291	0,7382	0,7445	0,964		Algorithm converged.	0,775	1,198
		Protocol amendment B	134	7,4	44	32,8	136	7,5	46	33,8	0,96		Algorithm converged.	0,58	1,59	-0,010		Algorithm converged.	-0,122	0,103	0,971		Algorithm converged.	0,693	1,361	0,8633		1,030		Algorithm converged.	0,735	1,444
	Nodal status	0 positive nodes	75	4,1	20	26,7	81	4,4	27	33,3	0,73		Algorithm converged.	0,36	1,45	-0,067		Algorithm converged.	-0,210	0,077	0,800		Algorithm converged.	0,492	1,300	0,3677	0,2842	1,250		Algorithm converged.	0,769	2,031
		>= 1 positive nodes	362	20,0	127	35,1	400	21,9	132	33,0	1,10		Algorithm converged.	0,81	1,48	0,021		Algorithm converged.	-0,047	0,088	1,063		Algorithm converged.	0,872	1,296	0,5442		0,941		Algorithm converged.	0,772	1,146
	Menopausal status at randomization	Premenopausal	284	15,7	91	32,0	330	18,1	113	34,2	0,91		Algorithm converged.	0,65	1,27	-0,022		Algorithm converged.	-0,097	0,053	0,936		Algorithm converged.	0,747	1,173	0,5645	0,1728	1,069		Algorithm converged.	0,853	1,340
		Postmenopausal	152	8,4	56	36,8	150	8,2	45	30,0	1,36		Algorithm converged.	0,84	2,20	0,068		Algorithm converged.	-0,038	0,175	1,228		Algorithm converged.	0,891	1,693	0,2098		0,814		Algorithm converged.	0,591	1,123

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO													PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Unknown/Missing	1	<0.1	0	0,0	1	<0.1	1	100,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,037	*	WARNING: The relative Hessian convergence criterion of 24.689720946 is greater than the limit of 0.0001. The convergence is questionable.	0,037	0,037	NE		27,161	*	WARNING: The relative Hessian convergence criterion of 24.689720946 is greater than the limit of 0.0001. The convergence is questionable.	27,161	27,161
	Age II	< 65	415	22,9	143	34,5	464	25,5	155	33,4	1,05		Algorithm converged.	0,79	1,39	0,011		Algorithm converged.	-0,052	0,073	1,032		Algorithm converged.	0,858	1,241	0,7420	-	0,969		Algorithm converged.	0,806	1,166
		>= 65	22	1,2	4	18,2	17	0,9	4	23,5	0,72		Algorithm converged.	0,15	3,43	-0,053		Algorithm converged.	-0,312	0,205	0,773		Algorithm converged.	0,225	2,651	0,6819		1,294		Algorithm converged.	0,377	4,441
	Histological grade	Grade 1	13	0,7	4	30,8	5	0,3	1	20,0	1,78		Algorithm converged.	0,15	21,39	0,108		Algorithm converged.	-0,323	0,539	1,538		Algorithm converged.	0,223	10,635	0,6623	-	0,650		Algorithm converged.	0,094	4,493
		Grade 2	130	7,2	35	26,9	148	8,1	53	35,8	0,66		Algorithm converged.	0,40	1,10	-0,089		Algorithm converged.	-0,197	0,020	0,752		Algorithm converged.	0,527	1,073	0,1163		1,330		Algorithm converged.	0,932	1,899
		Grade 3	283	15,6	104	36,7	319	17,5	102	32,0	1,24		Algorithm converged.	0,88	1,73	0,048		Algorithm converged.	-0,028	0,124	1,149		Algorithm converged.	0,921	1,434	0,2178		0,870		Algorithm converged.	0,697	1,086
		Unevaluable/Unknown/Missing	11	0,6	4	36,4	9	0,5	3	33,3	1,14		Algorithm converged.	0,18	7,28	0,030		Algorithm converged.	-0,389	0,449	1,091		Algorithm converged.	0,325	3,659	0,8879		0,917		Algorithm converged.	0,273	3,075
	Type of surgery for primary tumor	Breast conserving surgery	183	10,1	73	39,9	202	11,1	68	33,7	1,31		Algorithm converged.	0,86	1,98	0,062		Algorithm converged.	-0,034	0,159	1,185		Algorithm converged.	0,911	1,541	0,2057	0,1298	0,844		Algorithm converged.	0,649	1,098

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO													PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Mastectomy	254	14,0	74	29,1	279	15,3	91	32,6	0,85		Algorithm converged.	0,59	1,23	-0,035		Algorithm converged.	-0,113	0,044	0,893		Algorithm converged.	0,692	1,153	0,3862		1,120		Algorithm converged.	0,867	1,445
	Tumor size	0 - < 2 cm	182	10,0	63	34,6	189	10,4	63	33,3	1,06		Algorithm converged.	0,69	1,63	0,013		Algorithm converged.	-0,084	0,109	1,038		Algorithm converged.	0,782	1,379	0,7943	0,4680	0,963		Algorithm converged.	0,725	1,279
		>= 2 - < 5 cm	221	12,2	72	32,6	250	13,7	87	34,8	0,91		Algorithm converged.	0,62	1,33	-0,022		Algorithm converged.	-0,108	0,063	0,936		Algorithm converged.	0,726	1,207	0,6115		1,068		Algorithm converged.	0,828	1,378
		>= 5 cm	33	1,8	11	33,3	41	2,2	9	22,0	1,78		Algorithm converged.	0,63	5,00	0,114		Algorithm converged.	-0,091	0,319	1,519		Algorithm converged.	0,716	3,222	0,2765		0,659		Algorithm converged.	0,310	1,397
		Missing	1	<0.1	1	100,0	1	<0.1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE
	Loco-regional radiotherapy	Yes	355	19,6	124	34,9	386	21,2	129	33,4	1,07		Algorithm converged.	0,79	1,45	0,015		Algorithm converged.	-0,053	0,083	1,045		Algorithm converged.	0,856	1,277	0,6649	0,5200	0,957		Algorithm converged.	0,783	1,169
		No	82	4,5	23	28,0	95	5,2	30	31,6	0,84		Algorithm converged.	0,44	1,61	-0,035		Algorithm converged.	-0,170	0,100	0,888		Algorithm converged.	0,563	1,401	0,6103		1,126		Algorithm converged.	0,714	1,776
	Race	White	354	19,5	123	34,7	392	21,5	142	36,2	0,94		Algorithm converged.	0,69	1,27	-0,015		Algorithm converged.	-0,084	0,054	0,959		Algorithm converged.	0,790	1,165	0,6737	-	1,043		Algorithm converged.	0,859	1,266
		Black	7	0,4	4	57,1	8	0,4	2	25,0	4,00		Algorithm converged.	0,45	35,79	0,321		Algorithm converged.	-0,152	0,795	2,286		Algorithm converged.	0,586	8,914	0,2338		0,438		Algorithm converged.	0,112	1,706
		Asian	64	3,5	15	23,4	68	3,7	12	17,6	1,43		Algorithm converged.	0,61	3,34	0,058		Algorithm converged.	-0,080	0,196	1,328		Algorithm converged.	0,674	2,616	0,4120		0,753		Algorithm converged.	0,382	1,483
		Other	10	0,6	4	40,0	13	0,7	3	23,1	2,22		Algorithm converged.	0,36	13,54	0,169		Algorithm converged.	-0,211	0,550	1,733		Algorithm converged.	0,497	6,047	0,3882		0,577		Algorithm converged.	0,165	2,013

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	2	0,1	1	50,0	0	0,0	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	383	21,1	113	29,5	402	22,1	118	29,4	1,01		Algorithm converged.	0,74	1,37	0,002		Algorithm converged.	-0,062	0,065	1,005		Algorithm converged.	0,809	1,248	0,9631		0,995		Algorithm converged.	0,801	1,236
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	16	0,9	3	18,8	16	0,9	4	25,0	0,69		Algorithm converged.	0,13	3,75	-0,063		Algorithm converged.	-0,348	0,223	0,750		Algorithm converged.	0,199	2,827	0,6709	-	1,333		Algorithm converged.	0,354	5,026
		0 positive nodes, tumor > 1 cm	55	3,0	16	29,1	51	2,8	16	31,4	0,90		Algorithm converged.	0,39	2,06	-0,023		Algorithm converged.	-0,198	0,152	0,927		Algorithm converged.	0,520	1,654	0,7982		1,078		Algorithm converged.	0,605	1,924
		1-3 positive nodes	212	11,7	59	27,8	198	10,9	57	28,8	0,95		Algorithm converged.	0,62	1,47	-0,010		Algorithm converged.	-0,097	0,078	0,967		Algorithm converged.	0,710	1,316	0,8296		1,034		Algorithm converged.	0,760	1,408
		>= 4 positive nodes	100	5,5	35	35,0	137	7,5	41	29,9	1,26		Algorithm converged.	0,73	2,19	0,051		Algorithm converged.	-0,070	0,172	1,170		Algorithm converged.	0,808	1,693	0,4070		0,855		Algorithm converged.	0,591	1,238
	Adjuvant chemotherapy regimen	Anthracycline	309	17,1	92	29,8	325	17,8	98	30,2	0,98		Algorithm converged.	0,70	1,38	-0,004		Algorithm converged.	-0,075	0,068	0,987		Algorithm converged.	0,778	1,253	0,9168	0,7297	1,013		Algorithm converged.	0,798	1,285
		Non-anthracycline	74	4,1	21	28,4	77	4,2	20	26,0	1,13		Algorithm converged.	0,55	2,31	0,024		Algorithm converged.	-0,118	0,166	1,093		Algorithm converged.	0,648	1,843	0,7399		0,915		Algorithm converged.	0,543	1,544
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	169	9,3	48	28,4	178	9,8	55	30,9	0,89		Algorithm converged.	0,56	1,41	-0,025		Algorithm converged.	-0,121	0,071	0,919		Algorithm converged.	0,664	1,272	0,6113	0,4689	1,088		Algorithm converged.	0,786	1,506
		Positive (ER and/or PgR positive)	214	11,8	65	30,4	224	12,3	63	28,1	1,11		Algorithm converged.	0,74	1,68	0,022		Algorithm converged.	-0,063	0,108	1,080		Algorithm converged.	0,807	1,445	0,6050		0,926		Algorithm converged.	0,692	1,239
	Geographical region II	USA/Canada	65	3,6	24	36,9	65	3,6	19	29,2	1,42		Algorithm converged.	0,68	2,95	0,077		Algorithm converged.	-0,084	0,238	1,263		Algorithm converged.	0,771	2,070	0,3540	-	0,792		Algorithm converged.	0,483	1,297
		Western Europe	213	11,8	61	28,6	212	11,6	68	32,1	0,85		Algorithm converged.	0,56	1,29	-0,034		Algorithm converged.	-0,122	0,053	0,893		Algorithm converged.	0,669	1,192	0,4415		1,120		Algorithm converged.	0,839	1,495

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	52	2,9	15	28,8	83	4,6	21	25,3	1,20		Algorithm converged.	0,55	2,61	0,035		Algorithm converged.	-0,119	0,190	1,140		Algorithm converged.	0,648	2,005	0,6490		0,877		Algorithm converged.	0,499	1,543
		Latin America	9	0,5	2	22,2	12	0,7	3	25,0	0,86		Algorithm converged.	0,11	6,62	-0,028		Algorithm converged.	-0,394	0,338	0,889		Algorithm converged.	0,186	4,258	0,8829		1,125		Algorithm converged.	0,235	5,389
		Other	44	2,4	11	25,0	30	1,6	7	23,3	1,10		Algorithm converged.	0,37	3,25	0,017		Algorithm converged.	-0,182	0,215	1,071		Algorithm converged.	0,469	2,448	0,8700		0,933		Algorithm converged.	0,409	2,132
	Protocol version	Protocol A	279	15,4	85	30,5	282	15,5	83	29,4	1,05		Algorithm converged.	0,73	1,51	0,010		Algorithm converged.	-0,065	0,086	1,035		Algorithm converged.	0,804	1,333	0,7894	0,6476	0,966		Algorithm converged.	0,750	1,244
		Protocol amendment B	104	5,7	28	26,9	120	6,6	35	29,2	0,89		Algorithm converged.	0,50	1,61	-0,022		Algorithm converged.	-0,140	0,095	0,923		Algorithm converged.	0,605	1,408	0,7100		1,083		Algorithm converged.	0,710	1,652
	Nodal status	0 positive nodes	71	3,9	19	26,8	67	3,7	20	29,9	0,86		Algorithm converged.	0,41	1,80	-0,031		Algorithm converged.	-0,181	0,119	0,896		Algorithm converged.	0,527	1,526	0,6871	0,6405	1,115		Algorithm converged.	0,655	1,899
		>= 1 positive nodes	312	17,2	94	30,1	335	18,4	98	29,3	1,04		Algorithm converged.	0,74	1,46	0,009		Algorithm converged.	-0,062	0,079	1,030		Algorithm converged.	0,812	1,306	0,8077		0,971		Algorithm converged.	0,766	1,231
	Menopausal status at randomization	Premenopausal	253	14,0	78	30,8	274	15,0	79	28,8	1,10		Algorithm converged.	0,76	1,60	0,020		Algorithm converged.	-0,058	0,098	1,069		Algorithm converged.	0,823	1,390	0,6163	0,4215	0,935		Algorithm converged.	0,720	1,215
		Postmenopausal	129	7,1	35	27,1	127	7,0	39	30,7	0,84		Algorithm converged.	0,49	1,44	-0,036		Algorithm converged.	-0,147	0,075	0,884		Algorithm converged.	0,601	1,298	0,5284		1,132		Algorithm converged.	0,770	1,663
		Unknown/Missing	1	<0.1	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Age II	< 65	361	19,9	108	29,9	388	21,3	113	29,1	1,04		Algorithm converged.	0,76	1,42	0,008		Algorithm converged.	-0,057	0,073	1,027		Algorithm converged.	0,823	1,282	0,8120	0,3828	0,973		Algorithm converged.	0,780	1,215
		>= 65	22	1,2	5	22,7	14	0,8	5	35,7	0,53		Algorithm converged.	0,12	2,32	-0,130		Algorithm converged.	-0,436	0,176	0,636		Algorithm converged.	0,224	1,806	0,3956		1,571		Algorithm converged.	0,554	4,459
	Histological grade	Grade 1	10	0,6	3	30,0	4	0,2	1	25,0	1,29		Algorithm converged.	0,09	17,95	0,050		Algorithm converged.	-0,461	0,561	1,200		Algorithm converged.	0,172	8,380	0,8541	-	0,833		Algorithm converged.	0,119	5,820
		Grade 2	108	6,0	24	22,2	134	7,4	42	31,3	0,63		Algorithm converged.	0,35	1,12	-0,091		Algorithm converged.	-0,202	0,020	0,709		Algorithm converged.	0,460	1,093	0,1193		1,410		Algorithm converged.	0,915	2,174

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Grade 3	259	14,3	82	31,7	256	14,0	71	27,7	1,21		Algorithm converged.	0,83	1,76	0,039		Algorithm converged.	-0,040	0,118	1,142		Algorithm converged.	0,874	1,490	0,3305		0,876		Algorithm converged.	0,671	1,144
		Unevaluable/Unknown/Missing	6	0,3	4	66,7	8	0,4	4	50,0	2,00		Algorithm converged.	0,22	17,89	0,167		Algorithm converged.	-0,346	0,679	1,333		Algorithm converged.	0,545	3,262	0,5285		0,750		Algorithm converged.	0,307	1,835
	Type of surgery for primary tumor	Breast conserving surgery	167	9,2	45	26,9	166	9,1	52	31,3	0,81		Algorithm converged.	0,50	1,30	-0,044		Algorithm converged.	-0,141	0,054	0,860		Algorithm converged.	0,615	1,204	0,3801	0,2303	1,163		Algorithm converged.	0,831	1,627
		Mastectomy	216	11,9	68	31,5	236	12,9	66	28,0	1,18		Algorithm converged.	0,79	1,77	0,035		Algorithm converged.	-0,049	0,120	1,126		Algorithm converged.	0,847	1,495	0,4138		0,888		Algorithm converged.	0,669	1,180
	Tumor size	0 - < 2 cm	163	9,0	41	25,2	155	8,5	47	30,3	0,77		Algorithm converged.	0,47	1,26	-0,052		Algorithm converged.	-0,150	0,047	0,830		Algorithm converged.	0,581	1,185	0,3041	0,2851	1,206		Algorithm converged.	0,844	1,722
		>= 2 - < 5 cm	198	10,9	63	31,8	213	11,7	62	29,1	1,14		Algorithm converged.	0,75	1,73	0,027		Algorithm converged.	-0,062	0,116	1,093		Algorithm converged.	0,816	1,464	0,5507		0,915		Algorithm converged.	0,683	1,226
		>= 5 cm	22	1,2	9	40,9	33	1,8	9	27,3	1,85		Algorithm converged.	0,59	5,80	0,136		Algorithm converged.	-0,119	0,392	1,500		Algorithm converged.	0,708	3,176	0,2894		0,667		Algorithm converged.	0,315	1,411
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	299	16,5	90	30,1	325	17,8	97	29,8	1,01		Algorithm converged.	0,72	1,43	0,003		Algorithm converged.	-0,069	0,075	1,009		Algorithm converged.	0,793	1,282	0,9448	0,9873	0,992		Algorithm converged.	0,780	1,261
		No	84	4,6	23	27,4	77	4,2	21	27,3	1,01		Algorithm converged.	0,50	2,01	0,001		Algorithm converged.	-0,137	0,139	1,004		Algorithm converged.	0,606	1,662	0,9877		0,996		Algorithm converged.	0,602	1,649
	Race	White	318	17,6	95	29,9	324	17,8	98	30,2	0,98		Algorithm converged.	0,70	1,38	-0,004		Algorithm converged.	-0,075	0,067	0,988		Algorithm converged.	0,780	1,251	0,9180	-	1,012		Algorithm converged.	0,800	1,282
		Black	6	0,3	1	16,7	4	0,2	1	25,0	0,60		Algorithm converged.	0,03	13,58	-0,083		Algorithm converged.	-0,602	0,435	0,667		Algorithm converged.	0,057	7,852	0,7473		1,500		Algorithm converged.	0,127	17,667
		Asian	47	2,6	13	27,7	64	3,5	16	25,0	1,15		Algorithm converged.	0,49	2,69	0,027		Algorithm converged.	-0,140	0,193	1,106		Algorithm converged.	0,591	2,072	0,7522		0,904		Algorithm converged.	0,483	1,693
		Other	11	0,6	4	36,4	10	0,5	3	30,0	1,33		Algorithm converged.	0,21	8,29	0,064		Algorithm converged.	-0,338	0,465	1,212		Algorithm converged.	0,355	4,138	0,7588		0,825		Algorithm converged.	0,242	2,816

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Missing	1	<0.1	0	0,0	0	0,0	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC08_W15_SG.xls
26OCT2020 15:53

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Future Perspective Item
MODEL: Unstratified analysis
STUDY: BO25126
Responder Analysis: 15-Point Decrease Compared to Baseline (Worsening)

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO											PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
END OF TREATMENT	All	n/a	1518	83,8	272	17,9	1576	86,5	292	18,5	0,96		Algorithm converged.	0,80	1,15	-0,006		Algorithm converged.	-0,033	0,021		0,967		Algorithm converged.	0,833	1,123	0,6607		1,034		Algorithm converged.	0,891	1,201
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	42	2,3	13	31,0	35	1,9	9	25,7	1,30		Algorithm converged.	0,48	3,52	0,052		Algorithm converged.	-0,149	0,254		1,204		Algorithm converged.	0,585	2,478	0,6147	0,2652	0,831		Algorithm converged.	0,404	1,710
		0 positive nodes, tumor > 1 cm	220	12,1	29	13,2	245	13,4	45	18,4	0,67		Algorithm converged.	0,41	1,12	-0,052		Algorithm converged.	-0,118	0,014		0,718		Algorithm converged.	0,467	1,103	0,1303		1,393		Algorithm converged.	0,907	2,141
		1-3 positive nodes	762	42,1	159	20,9	782	42,9	152	19,4	1,09		Algorithm converged.	0,85	1,40	0,014		Algorithm converged.	-0,026	0,054		1,074		Algorithm converged.	0,880	1,309	0,4841		0,932		Algorithm converged.	0,764	1,136
		>= 4 positive nodes	494	27,3	71	14,4	514	28,2	86	16,7	0,84		Algorithm converged.	0,59	1,18	-0,024		Algorithm converged.	-0,068	0,021		0,859		Algorithm converged.	0,643	1,147	0,3027		1,164		Algorithm converged.	0,872	1,554
	Adjuvant chemotherapy regimen	Anthracycline	1215	67,1	211	17,4	1264	69,3	229	18,1	0,95		Algorithm converged.	0,77	1,17	-0,008		Algorithm converged.	-0,038	0,023		0,959		Algorithm converged.	0,809	1,136	0,6248	0,8292	1,043		Algorithm converged.	0,880	1,236
		Non-anthracycline	303	16,7	61	20,1	312	17,1	63	20,2	1,00		Algorithm converged.	0,67	1,48	-0,001		Algorithm converged.	-0,064	0,063		0,997		Algorithm converged.	0,728	1,366	0,9851		1,003		Algorithm converged.	0,732	1,374
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	740	40,9	117	15,8	741	40,6	138	18,6	0,82		Algorithm converged.	0,63	1,08	-0,028		Algorithm converged.	-0,067	0,010		0,849		Algorithm converged.	0,678	1,062	0,1525	0,1161	1,178		Algorithm converged.	0,941	1,474
		Positive (ER and/or PgR positive)	778	43,0	155	19,9	835	45,8	154	18,4	1,10		Algorithm converged.	0,86	1,41	0,015		Algorithm converged.	-0,024	0,053		1,080		Algorithm converged.	0,884	1,320	0,4505		0,926		Algorithm converged.	0,758	1,131

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO					PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Geographical region II	USA/Canada	213	11,8	44	20,7	218	12,0	45	20,6	1,00		Algorithm converged.	0,63	1,60	0,000		Algorithm converged.	-0,076	0,077	1,001		Algorithm converged.	0,691	1,449	0,9969	0,9600	0,999		Algorithm converged.	0,690	1,447
		Western Europe	646	35,7	115	17,8	669	36,7	122	18,2	0,97		Algorithm converged.	0,73	1,29	-0,004		Algorithm converged.	-0,046	0,037	0,976		Algorithm converged.	0,775	1,229	0,8377		1,024		Algorithm converged.	0,813	1,290
		Asia Pacific	460	25,4	77	16,7	486	26,7	91	18,7	0,87		Algorithm converged.	0,62	1,22	-0,020		Algorithm converged.	-0,069	0,029	0,894		Algorithm converged.	0,679	1,177	0,4251		1,119		Algorithm converged.	0,849	1,473
		Latin America	37	2,0	7	18,9	42	2,3	7	16,7	1,17		Algorithm converged.	0,37	3,71	0,023		Algorithm converged.	-0,147	0,192	1,135		Algorithm converged.	0,439	2,935	0,7937		0,881		Algorithm converged.	0,341	2,278
		Other	162	8,9	29	17,9	161	8,8	27	16,8	1,08		Algorithm converged.	0,61	1,93	0,011		Algorithm converged.	-0,071	0,094	1,067		Algorithm converged.	0,663	1,719	0,7884		0,937		Algorithm converged.	0,582	1,509
	Protocol version	Protocol A	1035	57,2	168	16,2	1080	59,2	188	17,4	0,92		Algorithm converged.	0,73	1,15	-0,012		Algorithm converged.	-0,044	0,020	0,932		Algorithm converged.	0,771	1,127	0,4703	0,5378	1,072		Algorithm converged.	0,887	1,297
		Protocol amendment B	483	26,7	104	21,5	496	27,2	104	21,0	1,03		Algorithm converged.	0,76	1,40	0,006		Algorithm converged.	-0,046	0,057	1,027		Algorithm converged.	0,807	1,307	0,8291		0,974		Algorithm converged.	0,765	1,239
	Nodal status	0 positive nodes	262	14,5	42	16,0	280	15,4	54	19,3	0,80		Algorithm converged.	0,51	1,25	-0,033		Algorithm converged.	-0,097	0,032	0,831		Algorithm converged.	0,576	1,199	0,3227	0,3725	1,203		Algorithm converged.	0,834	1,735
		>= 1 positive nodes	1256	69,4	230	18,3	1296	71,1	238	18,4	1,00		Algorithm converged.	0,82	1,22	-0,001		Algorithm converged.	-0,031	0,030	0,997		Algorithm converged.	0,847	1,175	0,9729		1,003		Algorithm converged.	0,851	1,181
	Menopausal status at randomization	Premenopausal	741	40,9	136	18,4	789	43,3	146	18,5	0,99		Algorithm converged.	0,76	1,28	-0,002		Algorithm converged.	-0,040	0,037	0,992		Algorithm converged.	0,803	1,225	0,9394	0,7223	1,008		Algorithm converged.	0,816	1,245
		Postmenopausal	773	42,7	135	17,5	780	42,8	145	18,6	0,93		Algorithm converged.	0,72	1,20	-0,011		Algorithm converged.	-0,049	0,027	0,939		Algorithm converged.	0,760	1,162	0,5642		1,064		Algorithm converged.	0,861	1,316
		Unknown/Missing	4	0,2	1	25,0	7	0,4	1	14,3	2,00		Algorithm converged.	0,09	44,35	0,107		Algorithm converged.	-0,390	0,604	1,750		Algorithm converged.	0,146	20,996	0,6589		0,571		Algorithm converged.	0,048	6,856
	Age II	< 65	1342	74,1	236	17,6	1404	77,0	258	18,4	0,95		Algorithm converged.	0,78	1,15	-0,008		Algorithm converged.	-0,037	0,021	0,957		Algorithm converged.	0,816	1,123	0,5900	0,7327	1,045		Algorithm converged.	0,891	1,226
		>= 65	176	9,7	36	20,5	172	9,4	34	19,8	1,04		Algorithm converged.	0,62	1,76	0,007		Algorithm converged.	-0,077	0,091	1,035		Algorithm converged.	0,681	1,573	0,8730		0,966		Algorithm converged.	0,636	1,469

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Histological grade	Grade 1	27	1,5	5	18,5	22	1,2	9	40,9	0,33		Algorithm converged.	0,09	1,19	-0,224		Algorithm converged.	-0,476	0,028	0,453		Algorithm converged.	0,177	1,156	0,0974	0,2174	2,209		Algorithm converged.	0,865	5,639
		Grade 2	471	26,0	87	18,5	484	26,5	86	17,8	1,05		Algorithm converged.	0,75	1,46	0,007		Algorithm converged.	-0,042	0,056	1,040		Algorithm converged.	0,794	1,361	0,7780		0,962		Algorithm converged.	0,735	1,260
		Grade 3	961	53,1	167	17,4	1011	55,5	187	18,5	0,93		Algorithm converged.	0,74	1,17	-0,011		Algorithm converged.	-0,045	0,023	0,940		Algorithm converged.	0,778	1,135	0,5178		1,064		Algorithm converged.	0,881	1,286
		Unevaluable/Unknown/Missing	59	3,3	13	22,0	59	3,2	10	16,9	1,38		Algorithm converged.	0,55	3,47	0,051		Algorithm converged.	-0,092	0,194	1,300		Algorithm converged.	0,619	2,728	0,4878		0,769		Algorithm converged.	0,367	1,614
	Type of surgery for primary tumor	Breast conserving surgery	599	33,1	110	18,4	588	32,3	115	19,6	0,93		Algorithm converged.	0,69	1,24	-0,012		Algorithm converged.	-0,057	0,033	0,939		Algorithm converged.	0,742	1,188	0,5999	0,7681	1,065		Algorithm converged.	0,842	1,348
		Mastectomy	919	50,7	162	17,6	987	54,1	177	17,9	0,98		Algorithm converged.	0,77	1,24	-0,003		Algorithm converged.	-0,037	0,031	0,983		Algorithm converged.	0,810	1,193	0,8618		1,017		Algorithm converged.	0,839	1,234
		Missing	0	0,0	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Tumor size	0 - < 2 cm	561	31,0	85	15,2	573	31,4	102	17,8	0,82		Algorithm converged.	0,60	1,13	-0,026		Algorithm converged.	-0,070	0,017	0,851		Algorithm converged.	0,654	1,107	0,2302	0,2054	1,175		Algorithm converged.	0,903	1,529
		>= 2 - < 5 cm	834	46,1	167	20,0	855	46,9	158	18,5	1,10		Algorithm converged.	0,87	1,41	0,015		Algorithm converged.	-0,022	0,053	1,084		Algorithm converged.	0,891	1,318	0,4210		0,923		Algorithm converged.	0,759	1,122
		>= 5 cm	121	6,7	20	16,5	146	8,0	32	21,9	0,71		Algorithm converged.	0,38	1,31	-0,054		Algorithm converged.	-0,148	0,040	0,754		Algorithm converged.	0,456	1,248	0,2725		1,326		Algorithm converged.	0,801	2,195
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1175	64,9	214	18,2	1190	65,3	214	18,0	1,02		Algorithm converged.	0,82	1,25	0,002		Algorithm converged.	-0,029	0,033	1,013		Algorithm converged.	0,853	1,202	0,8847	0,2860	0,987		Algorithm converged.	0,832	1,172
		No	343	18,9	58	16,9	386	21,2	78	20,2	0,80		Algorithm converged.	0,55	1,17	-0,033		Algorithm converged.	-0,089	0,023	0,837		Algorithm converged.	0,616	1,138	0,2556		1,195		Algorithm converged.	0,879	1,625
	Race	White	998	55,1	182	18,2	1045	57,3	189	18,1	1,01		Algorithm converged.	0,81	1,27	0,002		Algorithm converged.	-0,032	0,035	1,008		Algorithm converged.	0,839	1,212	0,9298	-	0,992		Algorithm converged.	0,825	1,192

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Black	21	1,2	1	4,8	26	1,4	6	23,1	0,17		Algorithm converged.	0,02	1,51	-0,183		Algorithm converged.	-0,369	0,003	0,206		Algorithm converged.	0,027	1,583	0,1290		4,846		Algorithm converged.	0,632	37,173
		Asian	449	24,8	79	17,6	457	25,1	88	19,3	0,90		Algorithm converged.	0,64	1,25	-0,017		Algorithm converged.	-0,067	0,034	0,914		Algorithm converged.	0,694	1,202	0,5193		1,094		Algorithm converged.	0,832	1,440
		Other	46	2,5	10	21,7	47	2,6	9	19,1	1,17		Algorithm converged.	0,43	3,22	0,026		Algorithm converged.	-0,138	0,190	1,135		Algorithm converged.	0,508	2,536	0,7570		0,881		Algorithm converged.	0,394	1,967
		Missing	4	0,2	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
FU MONTH 36	All	n/a	1340	74,0	191	14,3	1304	71,5	188	14,4	0,99		Algorithm converged.	0,79	1,23	-0,002		Algorithm converged.	-0,028	0,025	0,989		Algorithm converged.	0,821	1,191	0,9046		1,011		Algorithm converged.	0,839	1,219
	Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	43	2,4	10	23,3	35	1,9	5	14,3	1,82		Algorithm converged.	0,56	5,93	0,090		Algorithm converged.	-0,082	0,261	1,628		Algorithm converged.	0,613	4,322	0,3280	0,6294	0,614		Algorithm converged.	0,231	1,631
		0 positive nodes, tumor > 1 cm	208	11,5	28	13,5	218	12,0	35	16,1	0,81		Algorithm converged.	0,47	1,39	-0,026		Algorithm converged.	-0,093	0,041	0,838		Algorithm converged.	0,530	1,327	0,4520		1,193		Algorithm converged.	0,754	1,888
		1-3 positive nodes	684	37,8	104	15,2	641	35,2	95	14,8	1,03		Algorithm converged.	0,76	1,39	0,004		Algorithm converged.	-0,035	0,042	1,026		Algorithm converged.	0,794	1,326	0,8450		0,975		Algorithm converged.	0,754	1,260
		>= 4 positive nodes	405	22,4	49	12,1	410	22,5	53	12,9	0,93		Algorithm converged.	0,61	1,40	-0,008		Algorithm converged.	-0,054	0,037	0,936		Algorithm converged.	0,651	1,346	0,7210		1,068		Algorithm converged.	0,743	1,537
	Adjuvant chemotherapy regimen	Anthracycline	1069	59,0	150	14,0	1047	57,4	145	13,8	1,02		Algorithm converged.	0,79	1,30	0,002		Algorithm converged.	-0,028	0,031	1,013		Algorithm converged.	0,820	1,252	0,9034	0,6169	0,987		Algorithm converged.	0,799	1,220
		Non-anthracycline	271	15,0	41	15,1	257	14,1	43	16,7	0,89		Algorithm converged.	0,56	1,41	-0,016		Algorithm converged.	-0,078	0,046	0,904		Algorithm converged.	0,611	1,339	0,6150		1,106		Algorithm converged.	0,747	1,637
	Centrally assessed hormone receptor status	Negative (ER and PgR negative)	654	36,1	92	14,1	634	34,8	98	15,5	0,90		Algorithm converged.	0,66	1,22	-0,014		Algorithm converged.	-0,053	0,025	0,910		Algorithm converged.	0,700	1,184	0,4820	0,3830	1,099		Algorithm converged.	0,845	1,429

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Positive (ER and/or PgR positive)	686	37,9	99	14,4	670	36,8	90	13,4	1,09		Algorithm converged.	0,80	1,48	0,010		Algorithm converged.	-0,027	0,047	1,074		Algorithm converged.	0,824	1,400	0,5957		0,931		Algorithm converged.	0,714	1,213
	Geographical region II	USA/Canada	177	9,8	34	19,2	149	8,2	18	12,1	1,73		Algorithm converged.	0,93	3,21	0,071		Algorithm converged.	-0,007	0,149	1,590		Algorithm converged.	0,938	2,696	0,0852	0,2268	0,629		Algorithm converged.	0,371	1,066
		Western Europe	572	31,6	68	11,9	562	30,8	82	14,6	0,79		Algorithm converged.	0,56	1,12	-0,027		Algorithm converged.	-0,066	0,012	0,815		Algorithm converged.	0,604	1,099	0,1803		1,227		Algorithm converged.	0,910	1,656
		Asia Pacific	413	22,8	63	15,3	427	23,4	65	15,2	1,00		Algorithm converged.	0,69	1,46	0,000		Algorithm converged.	-0,048	0,049	1,002		Algorithm converged.	0,728	1,379	0,9898		0,998		Algorithm converged.	0,725	1,373
		Latin America	33	1,8	6	18,2	36	2,0	4	11,1	1,78		Algorithm converged.	0,45	6,96	0,071		Algorithm converged.	-0,096	0,238	1,636		Algorithm converged.	0,506	5,292	0,4108		0,611		Algorithm converged.	0,189	1,976
		Other	145	8,0	20	13,8	130	7,1	19	14,6	0,93		Algorithm converged.	0,47	1,84	-0,008		Algorithm converged.	-0,091	0,074	0,944		Algorithm converged.	0,528	1,688	0,8453		1,060		Algorithm converged.	0,592	1,895
	Protocol version	Protocol A	939	51,8	116	12,4	902	49,5	135	15,0	0,80		Algorithm converged.	0,61	1,05	-0,026		Algorithm converged.	-0,058	0,005	0,825		Algorithm converged.	0,655	1,040	0,1031	0,0071	1,212		Algorithm converged.	0,962	1,526
		Protocol amendment B	401	22,1	75	18,7	402	22,1	53	13,2	1,51		Algorithm converged.	1,03	2,22	0,055		Algorithm converged.	0,005	0,106	1,419		Algorithm converged.	1,027	1,960	0,0340		0,705		Algorithm converged.	0,510	0,974
	Nodal status	0 positive nodes	251	13,9	38	15,1	253	13,9	40	15,8	0,95		Algorithm converged.	0,59	1,54	-0,007		Algorithm converged.	-0,070	0,056	0,958		Algorithm converged.	0,637	1,440	0,8351	0,8607	1,044		Algorithm converged.	0,694	1,571
		>= 1 positive nodes	1089	60,1	153	14,0	1051	57,7	148	14,1	1,00		Algorithm converged.	0,78	1,27	0,000		Algorithm converged.	-0,030	0,029	0,998		Algorithm converged.	0,809	1,230	0,9829		1,002		Algorithm converged.	0,813	1,236
	Menopausal status at randomization	Premenopausal	650	35,9	94	14,5	651	35,7	98	15,1	0,95		Algorithm converged.	0,70	1,30	-0,006		Algorithm converged.	-0,044	0,033	0,961		Algorithm converged.	0,740	1,247	0,7633	0,7540	1,041		Algorithm converged.	0,802	1,352
		Postmenopausal	686	37,9	97	14,1	649	35,6	90	13,9	1,02		Algorithm converged.	0,75	1,39	0,003		Algorithm converged.	-0,035	0,040	1,020		Algorithm converged.	0,781	1,330	0,8860		0,981		Algorithm converged.	0,752	1,280
		Unknown/Missing	4	0,2	0	0,0	4	0,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO						PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Age II	< 65	1189	65,7	165	13,9	1167	64,0	168	14,4	0,96		Algorithm converged.	0,76	1,21	-0,005		Algorithm converged.	-0,033	0,023	0,964		Algorithm converged.	0,790	1,176	0,7179	0,4869	1,037		Algorithm converged.	0,850	1,266
		>= 65	151	8,3	26	17,2	137	7,5	20	14,6	1,22		Algorithm converged.	0,64	2,30	0,026		Algorithm converged.	-0,058	0,111	1,179		Algorithm converged.	0,691	2,014	0,5455		0,848		Algorithm converged.	0,496	1,448
	Histological grade	Grade 1	26	1,4	6	23,1	20	1,1	6	30,0	0,70		Algorithm converged.	0,19	2,62	-0,069		Algorithm converged.	-0,327	0,189	0,769		Algorithm converged.	0,292	2,029	0,5960	0,8834	1,300		Algorithm converged.	0,493	3,429
		Grade 2	423	23,4	55	13,0	400	21,9	52	13,0	1,00		Algorithm converged.	0,67	1,50	0,000		Algorithm converged.	-0,046	0,046	1,000		Algorithm converged.	0,702	1,424	0,9992		1,000		Algorithm converged.	0,702	1,424
		Grade 3	842	46,5	120	14,3	834	45,7	123	14,7	0,96		Algorithm converged.	0,73	1,26	-0,005		Algorithm converged.	-0,039	0,029	0,966		Algorithm converged.	0,766	1,219	0,7729		1,035		Algorithm converged.	0,820	1,306
		Unevaluable/Unknown/Missing	49	2,7	10	20,4	50	2,7	7	14,0	1,58		Algorithm converged.	0,55	4,54	0,064		Algorithm converged.	-0,084	0,212	1,458		Algorithm converged.	0,604	3,521	0,4023		0,686		Algorithm converged.	0,284	1,657
	Type of surgery for primary tumor	Breast conserving surgery	534	29,5	65	12,2	508	27,9	67	13,2	0,91		Algorithm converged.	0,63	1,31	-0,010		Algorithm converged.	-0,051	0,030	0,923		Algorithm converged.	0,671	1,270	0,6220	0,5892	1,084		Algorithm converged.	0,788	1,490
		Mastectomy	806	44,5	126	15,6	796	43,7	121	15,2	1,03		Algorithm converged.	0,79	1,36	0,004		Algorithm converged.	-0,031	0,040	1,028		Algorithm converged.	0,818	1,294	0,8109		0,972		Algorithm converged.	0,773	1,223
	Tumor size	0 - < 2 cm	510	28,2	66	12,9	479	26,3	68	14,2	0,90		Algorithm converged.	0,62	1,29	-0,013		Algorithm converged.	-0,055	0,030	0,912		Algorithm converged.	0,665	1,249	0,5645	0,3206	1,097		Algorithm converged.	0,801	1,503
		>= 2 - < 5 cm	731	40,4	111	15,2	710	38,9	97	13,7	1,13		Algorithm converged.	0,84	1,52	0,015		Algorithm converged.	-0,021	0,051	1,111		Algorithm converged.	0,864	1,430	0,4113		0,900		Algorithm converged.	0,699	1,158
		>= 5 cm	97	5,4	14	14,4	113	6,2	23	20,4	0,66		Algorithm converged.	0,32	1,37	-0,059		Algorithm converged.	-0,161	0,043	0,709		Algorithm converged.	0,387	1,300	0,2666		1,410		Algorithm converged.	0,769	2,586
		Missing	2	0,1	0	0,0	2	0,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Loco-regional radiotherapy	Yes	1023	56,5	147	14,4	992	54,4	128	12,9	1,13		Algorithm converged.	0,88	1,46	0,015		Algorithm converged.	-0,015	0,045	1,114		Algorithm converged.	0,893	1,388	0,3382	0,0411	0,898		Algorithm converged.	0,720	1,119
		No	317	17,5	44	13,9	312	17,1	60	19,2	0,68		Algorithm converged.	0,44	1,04	-0,054		Algorithm converged.	-0,111	0,004	0,722		Algorithm converged.	0,505	1,031	0,0728		1,385		Algorithm converged.	0,970	1,978

			PERTUZUMAB (N=1811)				PLACEBO (N=1823)				PERTUZUMAB vs. PLACEBO										PERTUZUMAB vs. PLACEBO							PLACEBO vs. PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Visit	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Race	White	876	48,4	121	13,8	858	47,1	121	14,1	0,98		Algorithm converged.	0,74	1,28	-0,003		Algorithm converged.	-0,036	0,030	0,979		Algorithm converged.	0,775	1,237	0,8618	-	1,021		Algorithm converged.	0,808	1,290
		Black	18	1,0	1	5,6	18	1,0	2	11,1	0,47		Algorithm converged.	0,04	5,71	-0,056		Algorithm converged.	-0,235	0,124	0,500		Algorithm converged.	0,050	5,036	0,5564		2,000		Algorithm converged.	0,199	20,146
		Asian	399	22,0	64	16,0	394	21,6	62	15,7	1,02		Algorithm converged.	0,70	1,50	0,003		Algorithm converged.	-0,048	0,054	1,019		Algorithm converged.	0,740	1,404	0,9068		0,981		Algorithm converged.	0,712	1,351
		Other	42	2,3	5	11,9	33	1,8	3	9,1	1,35		Algorithm converged.	0,30	6,12	0,028		Algorithm converged.	-0,110	0,167	1,310		Algorithm converged.	0,337	5,086	0,6969		0,764		Algorithm converged.	0,197	2,966
		Missing	5	0,3	0	0,0	1	<0.1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_rsp_26a_19DEC2016_CHON_FSC09_W15_SG.xls
26OCT2020 15:55

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Mixed Model for Repeated Measure (MMRM) Analysen

Stratifiziert

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Fatigue Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1761	1716	6,536	0,470	1823	1777	1748	6,329	0,470	0,206	0,501	-0,776	1,188

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC01_ST.xls
02SEP2020 8:49

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1764	1719	3,366	0,215	1823	1778	1749	3,180	0,215	0,186	0,238	-0,282	0,653

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC02_ST.xls
02SEP2020 8:51

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Pain Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1763	1719	-1,066	0,480	1823	1778	1749	-0,357	0,480	-0,709	0,511	-1,710	0,293

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC03_ST.xls
02SEP2020 8:53

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Dyspnea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1760	1715	6,785	0,444	1823	1775	1747	7,633	0,443	-0,848	0,474	-1,777	0,081

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC04_ST.xls
02SEP2020 8:56

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Insomnia Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1761	1717	1,912	0,596	1823	1774	1743	1,982	0,597	-0,070	0,634	-1,314	1,174

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC05_ST.xls
02SEP2020 8:58

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Appetite Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1763	1718	3,246	0,377	1823	1776	1747	1,776	0,377	1,471	0,416	0,656	2,286

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC06_ST.xls
02SEP2020 9:00

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Constipation Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1764	1719	1,703	0,415	1823	1775	1746	2,511	0,415	-0,808	0,446	-1,683	0,066

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC07_ST.xls
02SEP2020 9:03

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Diarrhea Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1757	1715	6,746	0,334	1823	1776	1747	2,661	0,334	4,085	0,376	3,348	4,823

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC08_ST.xls
02SEP2020 9:05

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Financial Difficulties Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1750	1706	-1,398	0,555	1823	1773	1744	-1,728	0,554	0,329	0,595	-0,836	1,495

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC09_ST.xls
02SEP2020 9:08

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Global Health Status
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1756	1713	-2,233	0,421	1823	1775	1745	-2,384	0,421	0,152	0,449	-0,728	1,032

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_GLHST_ST.xls
02SEP2020 8:47

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Physical Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1764	1720	-3,820	0,334	1823	1779	1749	-4,074	0,334	0,255	0,357	-0,446	0,955

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC01_ST.xls
02SEP2020 8:21

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Role Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1761	1717	2,361	0,497	1823	1775	1746	2,041	0,497	0,320	0,532	-0,722	1,362

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC02_ST.xls
02SEP2020 8:24

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Emotional Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1760	1717	5,551	0,457	1823	1778	1749	4,558	0,457	0,992	0,488	0,036	1,948

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC03_ST.xls
02SEP2020 8:27

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1761	1718	-6,956	0,454	1823	1778	1749	-7,200	0,453	0,244	0,484	-0,706	1,193

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC04_ST.xls
02SEP2020 8:29

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-C30 Social Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1760	1717	0,064	0,488	1823	1775	1746	-0,236	0,488	0,300	0,520	-0,719	1,319

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC05_ST.xls
02SEP2020 8:36

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1759	1716	10,728	0,318	1823	1773	1743	11,184	0,318	-0,455	0,344	-1,130	0,219

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC10_ST.xls
02SEP2020 9:11

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1757	1712	-3,455	0,340	1823	1770	1740	-4,559	0,340	1,104	0,366	0,386	1,822

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC11_ST.xls
02SEP2020 9:14

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1757	1712	-4,595	0,424	1823	1771	1740	-3,778	0,424	-0,817	0,453	-1,705	0,070

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC12_ST.xls
02SEP2020 9:16

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	280	249	6,355	2,368	1823	255	230	12,428	2,462	-6,073	2,505	-11,000	-1,146

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_SSC13_ST.xls
02SEP2020 9:18

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Body Image Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1744	1701	-5,009	0,529	1823	1760	1728	-6,284	0,529	1,275	0,567	0,164	2,386

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC06_ST.xls
02SEP2020 8:38

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1700	1652	-0,616	0,441	1823	1715	1678	-0,577	0,440	-0,039	0,479	-0,977	0,899

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC07_ST.xls
02SEP2020 8:41

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Sexual Enjoyment Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	712	638	-8,641	0,926	1823	747	673	-7,935	0,898	-0,706	1,013	-2,694	1,282

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC08_ST.xls
02SEP2020 8:43

POPULATION: HR negative or node positive ITT
ENDPOINT: Change from baseline, EORTC QLQ-BR23 Future Perspective Item
MODEL: Stratified analysis (stratification factors: nodal status and tumor size; adjuvant chemotherapy regimen; centrally assessed hormone receptor status; protocol version)
STUDY: BO25126
Analysis of MMRM

		PERTUZUMAB					PLACEBO					Difference between treatments (PERTUZUMAB - PLACEBO)			
		N			Statistics		N			Statistics		Statistics			
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL
All	n/a	1811	1746	1703	7,180	0,625	1823	1761	1731	5,606	0,625	1,574	0,669	0,263	2,884

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM. Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_26a_19DEC2016_CHON_FSC09_ST.xls
02SEP2020 8:45

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Rücklaufquoten

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Fatigue Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1761	97,2	22,825	19,482	1823	100,0	1777	97,5	23,754	20,543
END OF ANTHRACYCLINE	n/a	1432	79,1	1347	94,1	34,463	21,735	1446	79,3	1362	94,2	36,078	22,250
WEEK 13	n/a	1688	93,2	1605	95,1	38,588	23,640	1725	94,6	1638	95,0	39,031	23,843
WEEK 25	n/a	1645	90,8	1585	96,4	30,242	21,441	1688	92,6	1602	94,9	29,481	21,384
END OF TREATMENT	n/a	1794	99,1	1574	87,7	28,177	21,587	1811	99,3	1631	90,1	26,558	22,275
FU MONTH 18	n/a	1663	91,8	1484	89,2	24,165	21,069	1688	92,6	1477	87,5	24,483	21,325
FU MONTH 24	n/a	1633	90,2	1433	87,8	23,091	20,406	1638	89,9	1426	87,1	23,446	21,352
FU MONTH 36	n/a	1571	86,7	1392	88,6	21,492	20,813	1556	85,4	1354	87,0	23,191	21,654
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	15,873	17,421	43	100,0	40	93,0	22,500	24,458
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	36,201	23,997	26	60,5	25	96,2	41,556	24,903
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	39,646	20,807	40	93,0	39	97,5	41,880	25,294
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	30,233	20,620	38	88,4	35	92,1	32,381	20,412
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	25,000	16,965	42	97,7	37	88,1	26,126	21,471
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	19,312	15,532	39	90,7	36	92,3	28,395	26,620

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	19,251	15,062	39	90,7	34	87,2	27,778	20,515
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	17,778	16,817	39	90,7	37	94,9	21,021	17,130
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	19,489	18,854	278	100,0	271	97,5	21,607	19,740
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	34,016	20,742	203	73,0	191	94,1	36,591	23,105
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	234	94,4	37,607	22,593	263	94,6	253	96,2	40,799	22,914
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	29,552	20,227	256	92,1	247	96,5	28,228	21,112
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	28,292	21,854	276	99,3	255	92,4	26,492	23,126
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	22,854	21,507	259	93,2	232	89,6	24,952	20,896
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	22,169	21,613	256	92,1	230	89,8	21,739	21,850
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	20,465	19,874	251	90,3	227	90,4	21,953	21,423
BASELINE	1-3 positive nodes	907	100,0	884	97,5	22,895	19,533	900	100,0	877	97,4	23,869	20,529
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	665	93,3	33,718	21,903	707	78,6	668	94,5	35,720	21,379
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	38,778	23,908	854	94,9	805	94,3	38,675	23,280
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	30,079	21,759	836	92,9	789	94,4	29,116	20,562
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	27,934	21,415	897	99,7	815	90,9	26,551	22,053
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	24,405	21,424	852	94,7	746	87,6	24,278	20,562

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	23,359	20,816	830	92,2	726	87,5	23,416	20,888
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	21,529	21,771	794	88,2	669	84,3	23,186	21,194
BASELINE	>= 4 positive nodes	596	100,0	576	96,6	24,769	19,559	602	100,0	589	97,8	24,656	20,618
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	35,570	21,729	510	84,7	478	93,7	36,088	22,972
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	38,644	23,954	568	94,4	541	95,2	38,529	24,977
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	30,808	21,608	558	92,7	531	95,2	30,414	22,733
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	28,761	22,096	596	99,0	524	87,9	26,633	22,315
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	24,816	20,714	538	89,4	463	86,1	24,274	22,309
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	23,449	19,600	513	85,2	436	85,0	24,057	21,901
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	22,339	20,021	472	78,4	421	89,2	24,056	22,847
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1402	97,4	22,456	18,965	1448	100,0	1413	97,6	23,653	20,571
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1345	94,1	34,490	21,731	1444	99,7	1361	94,3	36,080	22,258
WEEK 13	Anthracycline containing regimen	1347	93,6	1291	95,8	37,878	23,308	1374	94,9	1303	94,8	38,134	23,617
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	30,125	21,476	1346	93,0	1277	94,9	28,987	21,517
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1258	88,0	28,246	21,426	1444	99,7	1306	90,4	26,242	22,598

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1183	89,0	24,340	20,863	1340	92,5	1181	88,1	24,457	21,500
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	23,530	20,612	1308	90,3	1137	86,9	23,414	21,601
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	21,707	20,726	1244	85,9	1088	87,5	23,024	22,066
BASELINE	Non-anthracycline containing regimen	372	100,0	359	96,5	24,265	21,351	375	100,0	364	97,1	24,145	20,454
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	33,333	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	41,507	24,782	351	93,6	335	95,4	42,521	24,425
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	30,692	21,331	342	91,2	325	95,0	31,419	20,772
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	27,901	22,246	367	97,9	325	88,6	27,829	20,913
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	23,477	21,883	348	92,8	296	85,1	24,587	20,652
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	21,329	19,493	330	88,0	289	87,6	23,568	20,378
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	20,641	21,169	312	83,2	266	85,3	23,872	19,904
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	22,288	19,630	858	100,0	840	97,9	23,327	20,341
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	34,977	21,389	661	77,0	620	93,8	36,953	22,779
WEEK 13	Negative (ER and PgR negative)	815	94,3	775	95,1	38,215	23,218	804	93,7	773	96,1	38,680	23,177
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	29,620	20,615	786	91,6	750	95,4	28,896	20,642
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	27,872	21,242	854	99,5	766	89,7	26,443	21,310
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	717	89,5	22,935	20,814	781	91,0	696	89,1	24,545	21,224
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	22,342	20,079	763	88,9	676	88,6	22,419	20,793
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	20,969	20,037	735	85,7	655	89,1	21,874	20,363
BASELINE	Positive (ER and/or PgR positive)	947	100,0	919	97,0	23,316	19,344	965	100,0	937	97,1	24,137	20,725
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	708	93,2	34,000	22,047	785	81,3	742	94,5	35,347	21,786
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	830	95,1	38,936	24,036	921	95,4	865	93,9	39,345	24,431
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	30,837	22,199	902	93,5	852	94,5	29,995	22,016
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	28,464	21,916	957	99,2	865	90,4	26,660	23,107
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	25,315	21,254	907	94,0	781	86,1	24,427	21,429
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	23,793	20,696	875	90,7	750	85,7	24,370	21,816

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	21,989	21,526	821	85,1	699	85,1	24,424	22,743
Geographical region II													
BASELINE	USA/Canada	265	100,0	260	98,1	23,718	22,396	260	100,0	254	97,7	26,028	23,223
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	35,294	21,175	111	42,7	105	94,6	39,365	24,119
WEEK 13	USA/Canada	242	91,3	229	94,6	43,523	24,817	236	90,8	224	94,9	43,948	24,560
WEEK 25	USA/Canada	234	88,3	225	96,2	31,580	23,010	230	88,5	219	95,2	30,746	22,565
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	27,189	24,447	255	98,1	229	89,8	26,371	22,420
FU MONTH 18	USA/Canada	238	89,8	194	81,5	24,055	23,300	231	88,8	181	78,4	23,174	22,298
FU MONTH 24	USA/Canada	231	87,2	188	81,4	22,577	22,777	224	86,2	177	79,0	22,097	20,100
FU MONTH 36	USA/Canada	223	84,2	180	80,7	20,617	21,565	205	78,8	156	76,1	22,650	23,166
BASELINE	Western Europe	827	100,0	787	95,2	23,090	20,245	822	100,0	787	95,7	22,335	21,567
END OF ANTHRACYCLINE	Western Europe	732	88,5	669	91,4	36,904	22,956	728	88,6	663	91,1	37,816	23,942
WEEK 13	Western Europe	764	92,4	699	91,5	40,916	24,922	778	94,6	709	91,1	41,577	25,436
WEEK 25	Western Europe	738	89,2	693	93,9	33,125	23,224	750	91,2	681	90,8	30,511	23,125
END OF TREATMENT	Western Europe	821	99,3	693	84,4	31,457	23,240	817	99,4	706	86,4	28,360	24,858
FU MONTH 18	Western Europe	754	91,2	648	85,9	26,612	23,207	764	92,9	631	82,6	26,395	23,355
FU MONTH 24	Western Europe	739	89,4	614	83,1	25,172	22,041	747	90,9	620	83,0	24,552	23,797
FU MONTH 36	Western Europe	713	86,2	613	86,0	23,699	23,125	712	86,6	599	84,1	23,984	23,489
BASELINE	Asia Pacific	490	100,0	487	99,4	22,017	17,143	512	100,0	508	99,2	24,213	18,014
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	31,046	19,739	397	77,5	390	98,2	33,048	19,102
WEEK 13	Asia Pacific	466	95,1	465	99,8	34,922	20,868	493	96,3	492	99,8	34,440	20,615
WEEK 25	Asia Pacific	461	94,1	461	100,0	26,235	18,133	492	96,1	488	99,2	27,596	18,567

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	25,263	17,391	512	100,0	491	95,9	24,508	18,362
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	21,190	16,987	485	94,7	473	97,5	22,222	18,380
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	20,232	16,691	470	91,8	448	95,3	21,776	18,306
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	19,670	16,998	453	88,5	432	95,4	21,669	18,308
BASELINE	Latin America	43	100,0	43	100,0	14,212	13,997	47	100,0	46	97,9	19,082	15,829
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	21,456	16,246	32	68,1	32	100,0	27,778	14,665
WEEK 13	Latin America	40	93,0	40	100,0	33,056	20,975	44	93,6	44	100,0	34,091	20,669
WEEK 25	Latin America	39	90,7	39	100,0	21,937	16,419	44	93,6	44	100,0	20,960	15,196
END OF TREATMENT	Latin America	42	97,7	38	90,5	18,421	17,382	45	95,7	42	93,3	18,254	15,870
FU MONTH 18	Latin America	41	95,3	37	90,2	14,865	15,933	42	89,4	40	95,2	20,833	21,080
FU MONTH 24	Latin America	40	93,0	36	90,0	12,963	15,373	41	87,2	39	95,1	19,658	18,984
FU MONTH 36	Latin America	38	88,4	34	89,5	11,438	14,599	37	78,7	36	97,3	17,901	14,615
BASELINE	Other	186	100,0	184	98,9	24,577	18,195	182	100,0	182	100,0	26,618	19,112
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	34,104	20,529	178	97,8	172	96,6	35,788	21,116
WEEK 13	Other	176	94,6	172	97,7	33,753	21,944	174	95,6	169	97,1	36,489	22,944
WEEK 25	Other	173	93,0	167	96,5	29,474	18,773	172	94,5	170	98,8	31,340	20,792
END OF TREATMENT	Other	185	99,5	162	87,6	26,097	19,786	182	100,0	163	89,6	27,335	21,605
FU MONTH 18	Other	171	91,9	153	89,5	24,982	18,959	166	91,2	152	91,6	26,096	19,150
FU MONTH 24	Other	169	90,9	154	91,1	25,974	19,689	156	85,7	142	91,0	26,604	20,669
FU MONTH 36	Other	160	86,0	147	91,9	20,862	19,675	149	81,9	131	87,9	26,675	22,418
Protocol version													
BASELINE	Protocol A	1240	100,0	1206	97,3	22,416	19,634	1246	100,0	1211	97,2	23,089	20,146

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	918	93,3	33,830	21,674	988	79,3	928	93,9	36,572	22,590
WEEK 13	Protocol A	1155	93,1	1106	95,8	37,784	23,794	1180	94,7	1113	94,3	39,163	24,290
WEEK 25	Protocol A	1125	90,7	1087	96,6	29,674	21,394	1157	92,9	1093	94,5	29,231	21,355
END OF TREATMENT	Protocol A	1229	99,1	1074	87,4	27,436	21,870	1236	99,2	1118	90,5	26,088	22,074
FU MONTH 18	Protocol A	1142	92,1	1024	89,7	23,839	21,490	1156	92,8	1006	87,0	24,531	21,341
FU MONTH 24	Protocol A	1124	90,6	995	88,5	22,669	20,870	1127	90,4	981	87,0	22,907	21,336
FU MONTH 36	Protocol A	1087	87,7	980	90,2	21,032	21,168	1069	85,8	936	87,6	22,442	21,638
BASELINE	Protocol Amendment B	571	100,0	555	97,2	23,714	19,136	577	100,0	566	98,1	25,177	21,315
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	35,820	21,829	458	79,4	434	94,8	35,023	21,491
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	40,370	23,217	545	94,5	525	96,3	38,751	22,886
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	31,481	21,513	531	92,0	509	95,9	30,015	21,458
END OF TREATMENT	Protocol Amendment B	565	98,9	500	88,5	29,767	20,898	575	99,7	513	89,2	27,583	22,694
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	24,891	20,104	532	92,2	471	88,5	24,381	21,314
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	24,049	19,298	511	88,6	445	87,1	24,632	21,363
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	22,586	19,926	487	84,4	418	85,8	24,867	21,622
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	18,900	18,649	321	100,0	311	96,9	21,722	20,365
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	34,339	21,206	229	71,3	216	94,3	37,166	23,314
WEEK 13	0 positive nodes	294	95,5	278	94,6	37,930	22,297	303	94,4	292	96,4	40,944	23,203
WEEK 25	0 positive nodes	287	93,2	281	97,9	29,656	20,252	294	91,6	282	95,9	28,743	21,035
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	27,757	21,144	318	99,1	292	91,8	26,446	22,888
FU MONTH 18	0 positive nodes	292	94,8	262	89,7	22,286	20,681	298	92,8	268	89,9	25,415	21,726

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	21,671	20,646	295	91,9	264	89,5	22,517	21,740
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	20,000	19,376	290	90,3	264	91,0	21,822	20,848
BASELINE	>= 1 positive nodes	1503	100,0	1460	97,1	23,634	19,558	1502	100,0	1466	97,6	24,185	20,561
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1137	94,0	34,486	21,841	1217	81,0	1146	94,2	35,874	22,048
WEEK 13	>= 1 positive nodes	1394	92,7	1327	95,2	38,726	23,917	1422	94,7	1346	94,7	38,616	23,967
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	30,368	21,694	1394	92,8	1320	94,7	29,638	21,463
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1303	87,5	28,264	21,684	1493	99,4	1339	89,7	26,583	22,147
FU MONTH 18	>= 1 positive nodes	1371	91,2	1222	89,1	24,568	21,138	1390	92,5	1209	87,0	24,276	21,239
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	23,394	20,350	1343	89,4	1162	86,5	23,657	21,267
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	21,835	21,123	1266	84,3	1090	86,1	23,522	21,841
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	23,681	19,497	885	100,0	867	98,0	23,658	20,084
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	34,525	21,742	726	82,0	693	95,5	35,065	21,685
WEEK 13	Premenopausal	841	96,3	806	95,8	38,179	23,302	852	96,3	809	95,0	38,223	23,077
WEEK 25	Premenopausal	825	94,5	800	97,0	31,028	21,808	838	94,7	799	95,3	29,259	20,640
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	27,756	21,502	881	99,5	813	92,3	24,880	21,762
FU MONTH 18	Premenopausal	819	93,8	724	88,4	23,404	20,706	835	94,4	740	88,6	22,688	20,535
FU MONTH 24	Premenopausal	803	92,0	705	87,8	22,467	19,982	807	91,2	708	87,7	21,626	20,069

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	20,901	21,491	773	87,3	669	86,5	21,599	21,053
BASELINE	Postmenopausal	933	100,0	903	96,8	22,081	19,454	929	100,0	902	97,1	23,836	20,971
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	666	92,6	34,459	21,785	711	76,5	662	93,1	37,101	22,828
WEEK 13	Postmenopausal	842	90,2	795	94,4	39,029	24,040	864	93,0	821	95,0	39,762	24,616
WEEK 25	Postmenopausal	815	87,4	780	95,7	29,530	21,062	841	90,5	796	94,6	29,753	22,170
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	28,593	21,723	921	99,1	810	87,9	28,230	22,715
FU MONTH 18	Postmenopausal	839	89,9	757	90,2	24,916	21,434	844	90,9	729	86,4	26,223	21,981
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	23,780	20,801	823	88,6	713	86,6	25,261	22,392
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	22,075	20,171	776	83,5	679	87,5	24,800	22,182
BASELINE	Unknown/Missing	5	100,0	5	100,0	11,111	15,713	9	100,0	8	88,9	25,000	23,570
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	26,667	14,907	9	100,0	7	77,8	39,683	20,141
WEEK 13	Unknown/Missing	5	100,0	4	80,0	33,333	0,000	9	100,0	8	88,9	45,833	17,252
WEEK 25	Unknown/Missing	5	100,0	5	100,0	15,556	12,669	9	100,0	7	77,8	23,810	13,500
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	25,000	5,556	9	100,0	8	88,9	27,778	17,817
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	18,519	6,415	9	100,0	8	88,9	31,944	20,086
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	8	88,9	5	62,5	22,222	28,328
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	7	77,8	6	85,7	18,519	15,181
Age II													
BASELINE	< 65	1581	100,0	1542	97,5	23,134	19,332	1604	100,0	1569	97,8	23,773	20,129
END OF ANTHRACYCLINE	< 65	1268	80,2	1199	94,6	34,140	21,635	1287	80,2	1220	94,8	36,025	21,975
WEEK 13	< 65	1497	94,7	1428	95,4	37,823	23,157	1529	95,3	1455	95,2	38,870	23,679

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	30,171	21,470	1501	93,6	1429	95,2	29,578	21,179
END OF TREATMENT	< 65	1569	99,2	1385	88,3	27,481	21,045	1596	99,5	1448	90,7	26,450	22,128
FU MONTH 18	< 65	1474	93,2	1313	89,1	23,970	21,076	1497	93,3	1320	88,2	24,339	21,176
FU MONTH 24	< 65	1446	91,5	1263	87,3	22,754	20,235	1450	90,4	1270	87,6	23,097	21,073
FU MONTH 36	< 65	1390	87,9	1234	88,8	21,070	20,644	1383	86,2	1206	87,2	23,070	21,496
BASELINE	>= 65	230	100,0	219	95,2	20,649	20,424	219	100,0	208	95,0	23,611	23,485
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	37,087	22,431	159	72,6	142	89,3	36,541	24,565
WEEK 13	>= 65	191	83,0	177	92,7	44,758	26,496	196	89,5	183	93,4	40,316	25,133
WEEK 25	>= 65	181	78,7	178	98,3	30,805	21,260	187	85,4	173	92,5	28,677	23,060
END OF TREATMENT	>= 65	225	97,8	189	84,0	33,275	24,673	215	98,2	183	85,1	27,413	23,452
FU MONTH 18	>= 65	189	82,2	171	90,5	25,666	21,014	191	87,2	157	82,2	25,690	22,579
FU MONTH 24	>= 65	187	81,3	170	90,9	25,588	21,532	188	85,8	156	83,0	26,282	23,378
FU MONTH 36	>= 65	181	78,7	158	87,3	24,789	21,880	173	79,0	148	85,5	24,174	22,955
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	25,806	20,765	24	100,0	24	100,0	23,148	22,202
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	41,176	28,264	17	70,8	16	94,1	36,806	27,131
WEEK 13	Grade 1	31	96,9	30	96,8	45,185	29,748	23	95,8	22	95,7	37,879	26,706
WEEK 25	Grade 1	31	96,9	29	93,5	40,038	32,305	23	95,8	22	95,7	30,808	24,471
END OF TREATMENT	Grade 1	31	96,9	27	87,1	28,807	25,273	24	100,0	22	91,7	28,283	26,053
FU MONTH 18	Grade 1	30	93,8	26	86,7	28,632	28,140	23	95,8	22	95,7	24,242	23,666
FU MONTH 24	Grade 1	28	87,5	27	96,4	27,160	24,717	23	95,8	21	91,3	22,751	22,076
FU MONTH 36	Grade 1	27	84,4	26	96,3	23,504	25,978	22	91,7	20	90,9	27,222	21,471
BASELINE	Grade 2	552	100,0	536	97,1	21,092	17,471	557	100,0	543	97,5	23,399	20,125
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	32,888	20,715	446	80,1	424	95,1	35,312	21,398

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	37,365	23,236	524	94,1	504	96,2	37,643	23,128
WEEK 25	Grade 2	494	89,5	479	97,0	27,441	20,564	515	92,5	493	95,7	28,713	20,713
END OF TREATMENT	Grade 2	548	99,3	485	88,5	26,506	21,385	553	99,3	496	89,7	26,971	22,605
FU MONTH 18	Grade 2	507	91,8	457	90,1	22,636	20,619	517	92,8	448	86,7	23,500	20,444
FU MONTH 24	Grade 2	501	90,8	449	89,6	22,210	20,183	500	89,8	431	86,2	22,686	21,374
FU MONTH 36	Grade 2	487	88,2	438	89,9	19,305	20,116	476	85,5	414	87,0	22,450	21,915
BASELINE	Grade 3	1161	100,0	1131	97,4	23,519	20,172	1173	100,0	1142	97,4	23,910	20,887
END OF ANTHRACYCLINE	Grade 3	918	79,1	858	93,5	35,302	22,029	919	78,3	860	93,6	36,680	22,868
WEEK 13	Grade 3	1088	93,7	1029	94,6	38,862	23,660	1114	95,0	1052	94,4	39,750	24,161
WEEK 25	Grade 3	1059	91,2	1019	96,2	31,442	21,255	1087	92,7	1025	94,3	29,946	21,901
END OF TREATMENT	Grade 3	1150	99,1	1001	87,0	28,866	21,322	1165	99,3	1053	90,4	26,374	22,147
FU MONTH 18	Grade 3	1067	91,9	947	88,8	24,727	20,839	1085	92,5	948	87,4	24,848	21,643
FU MONTH 24	Grade 3	1046	90,1	903	86,3	23,570	20,209	1053	89,8	918	87,2	23,747	21,549
FU MONTH 36	Grade 3	1002	86,3	876	87,4	22,634	20,819	999	85,2	868	86,9	23,355	21,744
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	23,633	21,815	69	100,0	68	98,6	24,183	17,588
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	31,019	21,980	64	92,8	62	96,9	32,796	17,473
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	40,437	22,954	64	92,8	60	93,8	38,519	23,096
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	27,395	22,340	63	91,3	62	98,4	27,419	16,433
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	29,872	25,300	69	100,0	60	87,0	25,741	20,711
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	25,103	24,532	63	91,3	59	93,7	26,177	22,103

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	20,370	23,020	62	89,9	56	90,3	24,603	17,691
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	19,658	22,613	59	85,5	52	88,1	24,786	18,093
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	20,987	19,046	715	100,0	687	96,1	22,158	21,378
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	548	92,6	35,726	22,794	572	80,0	522	91,3	36,952	22,854
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	40,485	25,256	673	94,1	634	94,2	41,080	24,311
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	32,820	22,973	654	91,5	613	93,7	31,077	22,403
END OF TREATMENT	Breast conserving surgery	722	99,2	624	86,4	29,817	22,964	711	99,4	623	87,6	27,813	23,903
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	24,832	22,069	659	92,2	561	85,1	24,777	21,418
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	25,048	21,739	644	90,1	555	86,2	24,064	21,557
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	22,420	21,535	616	86,2	537	87,2	23,257	21,731
BASELINE	Mastectomy	1083	100,0	1055	97,4	24,055	19,682	1107	100,0	1089	98,4	24,742	19,943
END OF ANTHRACYCLINE	Mastectomy	840	77,6	799	95,1	33,598	20,948	873	78,9	839	96,1	35,538	21,875
WEEK 13	Mastectomy	1011	93,4	968	95,7	37,339	22,439	1051	94,9	1003	95,4	37,753	23,469
WEEK 25	Mastectomy	980	90,5	946	96,5	28,500	20,167	1033	93,3	988	95,6	28,486	20,687
END OF TREATMENT	Mastectomy	1072	99,0	950	88,6	27,099	20,573	1099	99,3	1007	91,6	25,720	21,098
FU MONTH 18	Mastectomy	985	91,0	890	90,4	23,720	20,375	1028	92,9	915	89,0	24,244	21,216
FU MONTH 24	Mastectomy	967	89,3	857	88,6	21,775	19,360	993	89,7	870	87,6	23,027	21,223

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	20,863	20,299	939	84,8	817	87,0	23,147	21,616
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	44,444	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	22,222	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	88,889	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	77,778	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	44,444	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	643	97,4	21,851	19,097	665	100,0	641	96,4	22,474	20,294
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	34,771	21,521	523	78,6	493	94,3	37,390	21,971
WEEK 13	0 - < 2 cm	620	93,9	582	93,9	39,796	22,944	631	94,9	605	95,9	39,816	23,732
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	30,608	21,590	617	92,8	588	95,3	29,384	21,109
END OF TREATMENT	0 - < 2 cm	655	99,2	578	88,2	28,672	21,799	661	99,4	599	90,6	26,164	22,016
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	23,877	20,600	624	93,8	561	89,9	24,371	21,413
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	22,680	20,496	606	91,1	530	87,5	23,417	21,250
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	20,593	20,497	580	87,2	507	87,4	22,376	21,380
BASELINE	>= 2 - < 5 cm	1009	100,0	979	97,0	23,005	19,402	991	100,0	971	98,0	24,425	20,903
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	756	94,9	34,164	21,663	789	79,6	743	94,2	35,808	22,525
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	37,703	23,779	940	94,9	891	94,8	39,419	23,652
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	29,766	21,370	919	92,7	865	94,1	30,071	21,596
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	27,291	21,047	985	99,4	878	89,1	26,670	22,203

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	23,782	20,992	914	92,2	785	85,9	24,855	21,331
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	23,595	20,700	889	89,7	777	87,4	23,967	21,558
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	21,967	20,942	839	84,7	729	86,9	23,731	21,907
BASELINE	>= 5 cm	139	100,0	137	98,6	26,277	21,511	165	100,0	163	98,8	24,267	18,692
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	35,450	23,373	132	80,0	124	93,9	31,989	21,091
WEEK 13	>= 5 cm	130	93,5	125	96,2	39,422	25,570	152	92,1	140	92,1	33,016	24,754
WEEK 25	>= 5 cm	124	89,2	119	96,0	32,166	21,356	150	90,9	147	98,0	25,964	20,347
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	32,178	23,940	163	98,8	152	93,3	27,010	23,159
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	28,453	23,554	148	89,7	129	87,2	22,567	20,691
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	21,922	17,882	141	85,5	117	83,0	19,658	19,757
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	22,772	21,452	135	81,8	116	85,9	23,084	21,090
BASELINE	Missing	3	100,0	2	66,7	11,111	15,713	2	100,0	2	100,0	66,667	15,713
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	25,926	23,130	2	100,0	2	100,0	66,667	15,713
WEEK 13	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	50,000	39,284
WEEK 25	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	61,111	54,997
END OF TREATMENT	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	61,111	54,997
FU MONTH 18	Missing	3	100,0	3	100,0	29,630	27,962	2	100,0	2	100,0	33,333	47,140
FU MONTH 24	Missing	3	100,0	3	100,0	7,407	6,415	2	100,0	2	100,0	50,000	39,284
FU MONTH 36	Missing	3	100,0	3	100,0	14,815	25,660	2	100,0	2	100,0	38,889	39,284
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1320	98,0	22,563	19,566	1350	100,0	1313	97,3	23,178	20,616
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	34,675	21,861	1104	81,8	1043	94,5	35,954	22,417
WEEK 13	Yes	1308	97,1	1244	95,1	38,925	23,971	1324	98,1	1250	94,4	38,996	24,061
WEEK 25	Yes	1277	94,8	1227	96,1	31,006	21,864	1302	96,4	1229	94,4	29,853	21,928

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1213	90,1	28,785	21,972	1350	100,0	1238	91,7	26,746	22,589
FU MONTH 18	Yes	1291	95,8	1144	88,6	24,490	21,259	1298	96,1	1133	87,3	24,130	21,406
FU MONTH 24	Yes	1266	94,0	1110	87,7	23,859	20,679	1260	93,3	1091	86,6	23,801	21,469
FU MONTH 36	Yes	1219	90,5	1062	87,1	21,887	20,739	1195	88,5	1038	86,9	23,239	21,820
BASELINE	No	464	100,0	441	95,0	23,608	19,231	473	100,0	464	98,1	25,383	20,267
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	33,724	21,307	342	72,3	319	93,3	36,486	21,724
WEEK 13	No	380	81,9	361	95,0	37,427	22,453	401	84,8	388	96,8	39,147	23,156
WEEK 25	No	368	79,3	358	97,3	27,623	19,728	386	81,6	373	96,6	28,254	19,462
END OF TREATMENT	No	447	96,3	361	80,8	26,131	20,132	461	97,5	393	85,2	25,968	21,271
FU MONTH 18	No	372	80,2	340	91,4	23,072	20,411	390	82,5	344	88,2	25,646	21,048
FU MONTH 24	No	367	79,1	323	88,0	20,451	19,235	378	79,9	335	88,6	22,289	20,955
FU MONTH 36	No	352	75,9	330	93,8	20,219	21,029	361	76,3	316	87,5	23,031	21,131
Race													
BASELINE	White	1252	100,0	1206	96,3	23,240	20,523	1255	100,0	1216	96,9	23,702	21,397
END OF ANTHRACYCLINE	White	1010	80,7	934	92,5	35,832	21,984	1018	81,1	941	92,4	37,236	23,133
WEEK 13	White	1158	92,5	1084	93,6	39,950	24,393	1183	94,3	1098	92,8	41,368	24,957
WEEK 25	White	1120	89,5	1063	94,9	32,032	22,578	1150	91,6	1072	93,2	30,343	22,496
END OF TREATMENT	White	1238	98,9	1049	84,7	29,314	22,927	1244	99,1	1091	87,7	27,788	23,929
FU MONTH 18	White	1138	90,9	980	86,1	25,385	22,344	1152	91,8	968	84,0	25,758	22,437
FU MONTH 24	White	1115	89,1	943	84,6	24,414	21,600	1120	89,2	941	84,0	24,548	22,714
FU MONTH 36	White	1071	85,5	923	86,2	22,469	22,355	1064	84,8	901	84,7	24,035	22,999
BASELINE	Black	25	100,0	24	96,0	16,667	16,051	31	100,0	30	96,8	30,370	25,924
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	30,864	16,460	15	48,4	15	100,0	43,704	27,688
WEEK 13	Black	21	84,0	17	81,0	41,830	26,796	29	93,5	28	96,6	45,238	24,740

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	30,994	23,593	29	93,5	28	96,6	33,333	21,383
END OF TREATMENT	Black	24	96,0	22	91,7	32,323	24,942	31	100,0	28	90,3	31,746	22,974
FU MONTH 18	Black	23	92,0	17	73,9	25,490	19,549	29	93,5	24	82,8	35,648	27,409
FU MONTH 24	Black	22	88,0	18	81,8	22,840	18,464	28	90,3	23	82,1	24,155	24,309
FU MONTH 36	Black	22	88,0	18	81,8	18,519	16,169	26	83,9	20	76,9	37,222	32,097
BASELINE	Asian	477	100,0	474	99,4	22,668	16,992	484	100,0	480	99,2	24,005	17,766
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	31,363	20,122	375	77,5	368	98,1	33,122	19,209
WEEK 13	Asian	455	95,4	450	98,9	35,395	21,221	466	96,3	465	99,8	34,002	20,099
WEEK 25	Asian	450	94,3	449	99,8	26,664	17,929	465	96,1	459	98,7	28,129	18,693
END OF TREATMENT	Asian	475	99,6	452	95,2	25,860	17,662	484	100,0	464	95,9	24,114	17,795
FU MONTH 18	Asian	447	93,7	434	97,1	21,761	17,280	461	95,2	444	96,3	21,659	17,988
FU MONTH 24	Asian	442	92,7	423	95,7	20,725	17,201	445	91,9	421	94,6	21,536	17,854
FU MONTH 36	Asian	424	88,9	402	94,8	19,873	16,876	425	87,8	398	93,6	21,357	17,604
BASELINE	Other	52	100,0	52	100,0	16,239	15,630	51	100,0	50	98,0	18,889	20,109
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	29,240	27,268	36	70,6	36	100,0	33,025	23,077
WEEK 13	Other	49	94,2	49	100,0	36,961	24,573	45	88,2	45	100,0	31,358	21,489
WEEK 25	Other	49	94,2	49	100,0	23,810	18,703	42	82,4	41	97,6	20,867	16,517
END OF TREATMENT	Other	52	100,0	47	90,4	23,404	21,137	50	98,0	47	94,0	19,385	18,602
FU MONTH 18	Other	50	96,2	48	96,0	20,023	23,113	44	86,3	39	88,6	18,519	18,962
FU MONTH 24	Other	49	94,2	45	91,8	18,272	21,076	43	84,3	39	90,7	17,664	18,683
FU MONTH 36	Other	49	94,2	44	89,8	16,414	18,169	39	76,5	33	84,6	15,152	14,385
BASELINE	Missing	5	100,0	5	100,0	35,556	18,257	2	100,0	1	50,0	11,111	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	48,889	23,040	2	100,0	2	100,0	33,333	15,713
WEEK 13	Missing	5	100,0	5	100,0	35,556	24,088	2	100,0	2	100,0	11,111	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	31,111	34,605	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	25,000	29,222	2	100,0	1	50,0	11,111	NE
FU MONTH 18	Missing	5	100,0	5	100,0	28,889	32,011	2	100,0	2	100,0	16,667	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	16,667	21,276	2	100,0	2	100,0	11,111	15,713
FU MONTH 36	Missing	5	100,0	5	100,0	26,667	37,351	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC01_SG.xls
11AUG2020 16:05

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1764	97,4	2,834	8,298	1823	100,0	1778	97,5	3,121	9,592
END OF ANTHRACYCLINE	n/a	1432	79,1	1347	94,1	14,118	19,072	1446	79,3	1363	94,3	15,028	20,160
WEEK 13	n/a	1688	93,2	1607	95,2	7,976	15,024	1725	94,6	1639	95,0	6,742	12,751
WEEK 25	n/a	1645	90,8	1585	96,4	3,975	10,409	1688	92,6	1602	94,9	3,485	10,143
END OF TREATMENT	n/a	1794	99,1	1575	87,8	3,492	9,967	1811	99,3	1631	90,1	3,209	9,695
FU MONTH 18	n/a	1663	91,8	1486	89,4	2,445	8,068	1688	92,6	1476	87,4	2,812	9,752
FU MONTH 24	n/a	1633	90,2	1432	87,7	2,723	8,919	1638	89,9	1426	87,1	2,922	9,305
FU MONTH 36	n/a	1571	86,7	1392	88,6	2,850	9,238	1556	85,4	1354	87,0	3,127	10,013
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	1,361	4,611	43	100,0	40	93,0	2,917	8,344
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	15,591	18,225	26	60,5	25	96,2	10,000	16,667
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	9,470	19,489	40	93,0	39	97,5	6,838	11,920
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	2,326	6,883	38	88,4	35	92,1	5,714	13,969
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	2,652	7,138	42	97,7	37	88,1	2,252	6,986
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	1,163	4,296	39	90,7	36	92,3	5,093	10,404

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	1,984	5,463	39	90,7	34	87,2	3,431	7,977
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	1,481	4,797	39	90,7	37	94,9	4,054	9,133
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	2,447	7,101	278	100,0	271	97,5	2,891	10,386
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	14,153	18,484	203	73,0	191	94,1	15,445	20,837
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	7,589	14,790	263	94,6	253	96,2	8,564	14,365
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	3,922	9,365	256	92,1	247	96,5	2,632	8,012
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	2,863	8,465	276	99,3	255	92,4	3,464	8,495
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	1,667	6,148	259	93,2	232	89,6	2,083	8,591
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	2,472	7,872	256	92,1	230	89,8	3,043	8,834
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	1,860	7,144	251	90,3	227	90,4	3,157	9,199
BASELINE	1-3 positive nodes	907	100,0	886	97,7	2,709	8,283	900	100,0	878	97,6	3,189	9,713
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	665	93,3	13,935	19,046	707	78,6	668	94,5	14,970	19,965
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	7,805	14,403	854	94,9	806	94,4	6,224	12,161
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	3,918	10,254	836	92,9	789	94,4	3,485	9,692
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	3,597	9,875	897	99,7	815	90,9	3,252	9,491
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	2,800	8,707	852	94,7	745	87,4	2,752	9,401

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	2,770	8,891	830	92,2	726	87,5	3,076	9,654
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	2,979	10,001	794	88,2	669	84,3	2,890	9,862
BASELINE	>= 4 positive nodes	596	100,0	577	96,8	3,322	9,003	602	100,0	589	97,8	3,141	9,120
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	14,266	19,431	510	84,7	479	93,9	15,205	20,346
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	8,286	15,658	568	94,4	541	95,2	6,654	12,825
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	4,223	11,315	558	92,7	531	95,2	3,735	11,316
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	3,679	10,880	596	99,0	524	87,9	3,085	10,687
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	2,371	8,060	538	89,4	463	86,1	3,096	10,745
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	2,833	9,662	513	85,2	436	85,0	2,561	9,066
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	3,279	9,188	472	78,4	421	89,2	3,405	10,741
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1404	97,6	2,493	7,714	1448	100,0	1413	97,6	2,890	9,559
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1345	94,1	14,139	19,078	1444	99,7	1362	94,3	15,002	20,145
WEEK 13	Anthracycline containing regimen	1347	93,6	1293	96,0	5,929	12,479	1374	94,9	1304	94,9	4,793	10,661
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	3,720	10,320	1346	93,0	1277	94,9	3,171	9,548
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1259	88,1	3,190	9,640	1444	99,7	1306	90,4	2,961	9,074

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1185	89,2	2,222	7,824	1340	92,5	1180	88,1	2,571	9,386
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	2,705	9,159	1308	90,3	1137	86,9	2,639	8,867
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	2,715	9,136	1244	85,9	1088	87,5	2,987	9,958
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	4,167	10,163	375	100,0	365	97,3	4,018	9,680
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	0,000	0,000	2	0,5	1	50,0	50,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	16,401	20,659	351	93,6	335	95,4	14,328	16,776
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	4,959	10,707	342	91,2	325	95,0	4,718	12,142
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	4,694	11,108	367	97,9	325	88,6	4,205	11,833
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	3,322	8,926	348	92,8	296	85,1	3,773	11,057
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	2,797	7,895	330	88,0	289	87,6	4,037	10,805
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	3,381	9,628	312	83,2	266	85,3	3,697	10,234
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	843	97,6	3,005	8,335	858	100,0	840	97,9	3,075	10,072
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	14,424	19,242	661	77,0	621	93,9	15,486	21,027
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	7,560	13,891	804	93,7	773	96,1	7,288	13,035
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	3,484	9,127	786	91,6	750	95,4	3,356	10,165
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	765	89,4	3,203	9,774	854	99,5	766	89,7	3,198	9,233
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	719	89,8	2,109	7,293	781	91,0	696	89,1	2,898	10,193
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	693	88,1	2,381	7,985	763	88,9	676	88,6	2,786	8,704
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	2,507	8,017	735	85,7	655	89,1	3,130	9,967
BASELINE	Positive (ER and/or PgR positive)	947	100,0	921	97,3	2,678	8,265	965	100,0	938	97,2	3,163	9,147
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	708	93,2	13,842	18,926	785	81,3	742	94,5	14,645	19,411
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	8,363	16,009	921	95,4	866	94,0	6,255	12,480
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	4,444	11,489	902	93,5	852	94,5	3,599	10,128
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	3,765	10,143	957	99,2	865	90,4	3,218	10,092
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	2,760	8,726	907	94,0	780	86,0	2,735	9,347
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	3,045	9,707	875	90,7	750	85,7	3,044	9,819

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	3,175	10,258	821	85,1	699	85,1	3,124	10,063
Geographical region II													
BASELINE	USA/Canada	265	100,0	260	98,1	4,423	10,288	260	100,0	255	98,1	5,359	12,089
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	14,869	21,864	111	42,7	105	94,6	13,333	16,408
WEEK 13	USA/Canada	242	91,3	229	94,6	12,737	18,902	236	90,8	224	94,9	10,045	16,005
WEEK 25	USA/Canada	234	88,3	225	96,2	6,222	14,026	230	88,5	219	95,2	4,947	11,158
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	4,301	9,725	255	98,1	229	89,8	4,440	10,515
FU MONTH 18	USA/Canada	238	89,8	194	81,5	3,694	10,422	231	88,8	181	78,4	4,696	12,084
FU MONTH 24	USA/Canada	231	87,2	188	81,4	3,369	8,816	224	86,2	177	79,0	3,390	10,710
FU MONTH 36	USA/Canada	223	84,2	180	80,7	3,796	10,836	205	78,8	156	76,1	3,846	11,492
BASELINE	Western Europe	827	100,0	790	95,5	2,511	7,851	822	100,0	787	95,7	2,605	9,205
END OF ANTHRACYCLINE	Western Europe	732	88,5	669	91,4	13,378	18,398	728	88,6	664	91,2	14,132	19,884
WEEK 13	Western Europe	764	92,4	700	91,6	6,214	13,545	778	94,6	710	91,3	5,704	11,229
WEEK 25	Western Europe	738	89,2	693	93,9	3,632	9,939	750	91,2	681	90,8	3,426	9,927
END OF TREATMENT	Western Europe	821	99,3	694	84,5	4,227	11,420	817	99,4	706	86,4	3,211	10,118
FU MONTH 18	Western Europe	754	91,2	650	86,2	2,462	8,374	764	92,9	630	82,5	2,725	10,126
FU MONTH 24	Western Europe	739	89,4	613	82,9	3,100	10,323	747	90,9	620	83,0	2,769	9,424
FU MONTH 36	Western Europe	713	86,2	613	86,0	3,399	10,684	712	86,6	599	84,1	3,144	10,507
BASELINE	Asia Pacific	490	100,0	487	99,4	2,704	8,219	512	100,0	508	99,2	3,182	9,493
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	16,176	20,251	397	77,5	390	98,2	16,496	20,802
WEEK 13	Asia Pacific	466	95,1	465	99,8	8,710	14,963	493	96,3	492	99,8	6,978	12,625
WEEK 25	Asia Pacific	461	94,1	461	100,0	3,254	8,598	492	96,1	488	99,2	2,801	9,440

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	2,550	8,419	512	100,0	491	95,9	2,240	6,865
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	1,917	6,752	485	94,7	473	97,5	2,008	6,867
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	2,079	6,841	470	91,8	448	95,3	2,641	7,714
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	2,073	7,093	453	88,5	432	95,4	2,623	8,080
BASELINE	Latin America	43	100,0	43	100,0	3,488	7,765	47	100,0	46	97,9	2,174	6,675
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	12,069	14,704	32	68,1	32	100,0	15,104	16,591
WEEK 13	Latin America	40	93,0	40	100,0	12,083	19,607	44	93,6	44	100,0	10,985	17,588
WEEK 25	Latin America	39	90,7	39	100,0	3,419	8,702	44	93,6	44	100,0	4,167	16,125
END OF TREATMENT	Latin America	42	97,7	38	90,5	2,632	11,960	45	95,7	42	93,3	5,952	17,585
FU MONTH 18	Latin America	41	95,3	37	90,2	2,703	7,363	42	89,4	40	95,2	4,167	14,495
FU MONTH 24	Latin America	40	93,0	36	90,0	2,778	9,344	41	87,2	39	95,1	3,846	9,719
FU MONTH 36	Latin America	38	88,4	34	89,5	2,941	6,449	37	78,7	36	97,3	2,778	7,454
BASELINE	Other	186	100,0	184	98,9	2,174	7,064	182	100,0	182	100,0	2,289	7,593
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	12,428	17,646	178	97,8	172	96,6	16,182	22,253
WEEK 13	Other	176	94,6	173	98,3	5,877	12,022	174	95,6	169	97,1	4,931	11,869
WEEK 25	Other	173	93,0	167	96,5	4,491	11,193	172	94,5	170	98,8	3,627	9,503
END OF TREATMENT	Other	185	99,5	162	87,6	2,160	6,200	182	100,0	163	89,6	3,681	10,802
FU MONTH 18	Other	171	91,9	153	89,5	2,288	6,909	166	91,2	152	91,6	3,070	10,922
FU MONTH 24	Other	169	90,9	154	91,1	2,273	8,100	156	85,7	142	91,0	3,638	11,249
FU MONTH 36	Other	160	86,0	147	91,9	1,587	5,631	149	81,9	131	87,9	3,944	12,024
Protocol version													
BASELINE	Protocol A	1240	100,0	1208	97,4	2,939	8,412	1246	100,0	1211	97,2	3,124	9,046

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	918	93,3	13,435	18,676	988	79,3	929	94,0	14,944	19,529
WEEK 13	Protocol A	1155	93,1	1108	95,9	7,656	14,494	1180	94,7	1114	94,4	6,942	12,665
WEEK 25	Protocol A	1125	90,7	1087	96,6	3,695	9,347	1157	92,9	1093	94,5	3,492	10,225
END OF TREATMENT	Protocol A	1229	99,1	1074	87,4	3,383	9,624	1236	99,2	1118	90,5	3,235	9,526
FU MONTH 18	Protocol A	1142	92,1	1026	89,8	2,290	7,888	1156	92,8	1005	86,9	2,769	9,457
FU MONTH 24	Protocol A	1124	90,6	994	88,4	2,800	9,114	1127	90,4	981	87,0	2,990	9,823
FU MONTH 36	Protocol A	1087	87,7	980	90,2	2,908	9,723	1069	85,8	936	87,6	3,205	10,362
BASELINE	Protocol Amendment B	571	100,0	556	97,4	2,608	8,047	577	100,0	567	98,3	3,116	10,675
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	15,579	19,835	458	79,4	434	94,8	15,207	21,472
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	8,684	16,131	545	94,5	525	96,3	6,317	12,934
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	4,585	12,405	531	92,0	509	95,9	3,471	9,974
END OF TREATMENT	Protocol Amendment B	565	98,9	501	88,7	3,726	10,671	575	99,7	513	89,2	3,151	10,063
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	2,790	8,454	532	92,2	471	88,5	2,902	10,363
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	2,549	8,466	511	88,6	445	87,1	2,772	8,054
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	2,710	7,975	487	84,4	418	85,8	2,951	9,194
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	2,270	6,764	321	100,0	311	96,9	2,894	10,135
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	14,365	18,409	229	71,3	216	94,3	14,815	20,439
WEEK 13	0 positive nodes	294	95,5	279	94,9	7,885	15,600	303	94,4	292	96,4	8,333	14,057
WEEK 25	0 positive nodes	287	93,2	281	97,9	3,677	9,037	294	91,6	282	95,9	3,014	8,991
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	2,829	8,252	318	99,1	292	91,8	3,311	8,318
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	1,584	5,881	298	92,8	268	89,9	2,488	8,894

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	251	86,6	2,390	7,516	295	91,9	264	89,5	3,093	8,715
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	1,795	6,790	290	90,3	264	91,0	3,283	9,178
BASELINE	>= 1 positive nodes	1503	100,0	1463	97,3	2,951	8,577	1502	100,0	1467	97,7	3,170	9,476
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1137	94,0	14,072	19,199	1217	81,0	1147	94,2	15,068	20,116
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	7,994	14,906	1422	94,7	1347	94,7	6,397	12,429
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	4,039	10,684	1394	92,8	1320	94,7	3,586	10,373
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1304	87,6	3,630	10,284	1493	99,4	1339	89,7	3,186	9,973
FU MONTH 18	>= 1 positive nodes	1371	91,2	1223	89,2	2,630	8,456	1390	92,5	1208	86,9	2,884	9,934
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	2,794	9,190	1343	89,4	1162	86,5	2,883	9,437
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	3,092	9,699	1266	84,3	1090	86,1	3,089	10,209
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	854	97,8	2,927	8,144	885	100,0	868	98,1	2,515	7,868
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	14,177	18,525	726	82,0	693	95,5	15,152	20,756
WEEK 13	Premenopausal	841	96,3	806	95,8	7,279	14,559	852	96,3	809	95,0	6,016	11,439
WEEK 25	Premenopausal	825	94,5	800	97,0	4,062	10,605	838	94,7	799	95,3	3,317	9,861
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	3,372	9,171	881	99,5	813	92,3	2,665	8,699
FU MONTH 18	Premenopausal	819	93,8	724	88,4	2,555	7,840	835	94,4	740	88,6	2,117	7,708
FU MONTH 24	Premenopausal	803	92,0	705	87,8	2,624	8,033	807	91,2	708	87,7	2,401	8,108

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	2,997	9,520	773	87,3	669	86,5	3,089	9,587
BASELINE	Postmenopausal	933	100,0	905	97,0	2,762	8,464	929	100,0	902	97,1	3,659	10,945
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	666	92,6	14,064	19,686	711	76,5	663	93,2	14,907	19,547
WEEK 13	Postmenopausal	842	90,2	797	94,7	8,678	15,483	864	93,0	822	95,1	7,502	13,929
WEEK 25	Postmenopausal	815	87,4	780	95,7	3,910	10,240	841	90,5	796	94,6	3,664	10,450
END OF TREATMENT	Postmenopausal	923	98,9	805	87,2	3,602	10,684	921	99,1	810	87,9	3,786	10,616
FU MONTH 18	Postmenopausal	839	89,9	759	90,5	2,350	8,298	844	90,9	728	86,3	3,503	11,445
FU MONTH 24	Postmenopausal	825	88,4	723	87,6	2,835	9,730	823	88,6	713	86,6	3,436	10,352
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	2,727	8,992	776	83,5	679	87,5	3,093	10,173
BASELINE	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	8	88,9	8,333	12,599
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	13,333	7,454	9	100,0	7	77,8	14,286	20,250
WEEK 13	Unknown/Missing	5	100,0	4	80,0	8,333	9,623	9	100,0	8	88,9	2,083	5,893
WEEK 25	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	7	77,8	2,381	6,299
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	4,167	8,333	9	100,0	8	88,9	0,000	0,000
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	9	100,0	8	88,9	4,167	7,715
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	8	88,9	5	62,5	3,333	7,454
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	7	77,8	6	85,7	11,111	27,217
Age II													
BASELINE	< 65	1581	100,0	1544	97,7	2,904	8,466	1604	100,0	1570	97,9	2,962	9,270
END OF ANTHRACYCLINE	< 65	1268	80,2	1199	94,6	14,248	19,060	1287	80,2	1221	94,9	15,493	20,255
WEEK 13	< 65	1497	94,7	1428	95,4	7,761	14,800	1529	95,3	1455	95,2	6,552	12,525

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	3,933	10,152	1501	93,6	1429	95,2	3,511	10,302
END OF TREATMENT	< 65	1569	99,2	1386	88,3	3,259	9,730	1596	99,5	1448	90,7	3,280	9,961
FU MONTH 18	< 65	1474	93,2	1314	89,1	2,359	7,909	1497	93,3	1320	88,2	2,778	9,509
FU MONTH 24	< 65	1446	91,5	1263	87,3	2,652	8,765	1450	90,4	1270	87,6	2,953	9,533
FU MONTH 36	< 65	1390	87,9	1234	88,8	2,674	8,806	1383	86,2	1206	87,2	3,179	10,187
BASELINE	>= 65	230	100,0	220	95,7	2,348	7,000	219	100,0	208	95,0	4,327	11,698
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	13,063	19,200	159	72,6	142	89,3	11,033	18,924
WEEK 13	>= 65	191	83,0	179	93,7	9,683	16,647	196	89,5	184	93,9	8,243	14,368
WEEK 25	>= 65	181	78,7	178	98,3	4,307	12,282	187	85,4	173	92,5	3,276	8,742
END OF TREATMENT	>= 65	225	97,8	189	84,0	5,203	11,440	215	98,2	183	85,1	2,641	7,246
FU MONTH 18	>= 65	189	82,2	172	91,0	3,101	9,195	191	87,2	156	81,7	3,098	11,640
FU MONTH 24	>= 65	187	81,3	169	90,4	3,254	10,006	188	85,8	156	83,0	2,671	7,208
FU MONTH 36	>= 65	181	78,7	158	87,3	4,219	12,036	173	79,0	148	85,5	2,703	8,486
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	4,839	11,542	24	100,0	24	100,0	4,167	10,132
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	17,647	23,914	17	70,8	16	94,1	8,333	13,608
WEEK 13	Grade 1	31	96,9	30	96,8	12,778	18,405	23	95,8	22	95,7	9,091	13,341
WEEK 25	Grade 1	31	96,9	29	93,5	8,621	20,712	23	95,8	22	95,7	2,273	7,793
END OF TREATMENT	Grade 1	31	96,9	27	87,1	1,852	7,061	24	100,0	22	91,7	4,545	11,708
FU MONTH 18	Grade 1	30	93,8	27	90,0	1,852	5,338	23	95,8	22	95,7	2,273	5,854
FU MONTH 24	Grade 1	28	87,5	27	96,4	3,086	6,597	23	95,8	21	91,3	6,349	11,151
FU MONTH 36	Grade 1	27	84,4	26	96,3	2,564	6,132	22	91,7	20	90,9	7,500	11,439
BASELINE	Grade 2	552	100,0	537	97,3	2,452	7,665	557	100,0	543	97,5	3,100	9,449
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	14,623	19,136	446	80,1	424	95,1	15,291	20,277

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	7,099	14,175	524	94,1	504	96,2	7,209	13,204
WEEK 25	Grade 2	494	89,5	479	97,0	2,958	8,887	515	92,5	493	95,7	3,178	8,829
END OF TREATMENT	Grade 2	548	99,3	485	88,5	3,402	9,958	553	99,3	496	89,7	3,360	9,411
FU MONTH 18	Grade 2	507	91,8	457	90,1	2,407	8,915	517	92,8	448	86,7	2,716	9,881
FU MONTH 24	Grade 2	501	90,8	449	89,6	2,450	8,564	500	89,8	431	86,2	3,016	10,099
FU MONTH 36	Grade 2	487	88,2	438	89,9	2,017	7,504	476	85,5	414	87,0	3,140	11,224
BASELINE	Grade 3	1161	100,0	1133	97,6	3,030	8,616	1173	100,0	1143	97,4	3,193	9,852
END OF ANTHRACYCLINE	Grade 3	918	79,1	858	93,5	14,161	19,152	919	78,3	861	93,7	15,176	20,461
WEEK 13	Grade 3	1088	93,7	1030	94,7	8,398	15,373	1114	95,0	1053	94,5	6,569	12,665
WEEK 25	Grade 3	1059	91,2	1019	96,2	4,432	10,743	1087	92,7	1025	94,3	3,756	10,937
END OF TREATMENT	Grade 3	1150	99,1	1002	87,1	3,709	10,206	1165	99,3	1053	90,4	3,166	9,938
FU MONTH 18	Grade 3	1067	91,9	948	88,8	2,584	7,890	1085	92,5	947	87,3	2,904	9,966
FU MONTH 24	Grade 3	1046	90,1	902	86,2	2,919	9,330	1053	89,8	918	87,2	2,832	8,934
FU MONTH 36	Grade 3	1002	86,3	876	87,4	3,349	10,152	999	85,2	868	86,9	3,053	9,469
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	1,587	4,932	69	100,0	68	98,6	1,716	5,102
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	7,639	13,734	64	92,8	62	96,9	12,903	16,088
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	5,464	13,166	64	92,8	60	93,8	5,000	9,848
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	2,011	7,035	63	91,3	62	98,4	1,882	6,114
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	1,366	6,306	69	100,0	60	87,0	2,222	6,485
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	0,617	3,177	63	91,3	59	93,7	2,260	5,755

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	1,543	4,876	62	89,9	56	90,3	2,381	8,058
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	1,603	6,812	59	85,5	52	88,1	2,564	7,659
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	2,408	7,354	715	100,0	687	96,1	2,960	9,007
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	548	92,6	13,443	18,928	572	80,0	523	91,4	14,723	20,056
WEEK 13	Breast conserving surgery	677	93,0	638	94,2	7,628	15,064	673	94,1	634	94,2	6,887	12,772
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	3,704	9,663	654	91,5	613	93,7	3,643	10,365
END OF TREATMENT	Breast conserving surgery	722	99,2	625	86,6	3,573	9,835	711	99,4	623	87,6	3,184	10,141
FU MONTH 18	Breast conserving surgery	678	93,1	596	87,9	2,209	7,248	659	92,2	561	85,1	2,793	10,309
FU MONTH 24	Breast conserving surgery	666	91,5	575	86,3	3,072	10,092	644	90,1	555	86,2	3,483	10,255
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	2,550	8,812	616	86,2	537	87,2	3,073	9,785
BASELINE	Mastectomy	1083	100,0	1058	97,7	3,119	8,864	1107	100,0	1090	98,5	3,226	9,950
END OF ANTHRACYCLINE	Mastectomy	840	77,6	799	95,1	14,581	19,168	873	78,9	839	96,1	15,236	20,240
WEEK 13	Mastectomy	1011	93,4	969	95,8	8,204	15,001	1051	94,9	1004	95,5	6,657	12,748
WEEK 25	Mastectomy	980	90,5	946	96,5	4,158	10,886	1033	93,3	988	95,6	3,391	10,011
END OF TREATMENT	Mastectomy	1072	99,0	950	88,6	3,439	10,057	1099	99,3	1007	91,6	3,227	9,418
FU MONTH 18	Mastectomy	985	91,0	890	90,4	2,603	8,574	1028	92,9	914	88,9	2,826	9,405
FU MONTH 24	Mastectomy	967	89,3	857	88,6	2,489	8,034	993	89,7	870	87,6	2,567	8,637

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	3,052	9,514	939	84,8	817	87,0	3,162	10,166
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	2,119	6,748	665	100,0	642	96,5	2,830	8,235
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	13,423	17,863	523	78,6	493	94,3	14,943	19,212
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	7,004	12,962	631	94,9	606	96,0	6,243	11,578
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	3,345	9,256	617	92,8	588	95,3	3,231	9,823
END OF TREATMENT	0 - < 2 cm	655	99,2	579	88,4	3,253	8,957	661	99,4	599	90,6	2,671	8,691
FU MONTH 18	0 - < 2 cm	617	93,5	546	88,5	1,618	5,794	624	93,8	560	89,7	2,530	9,085
FU MONTH 24	0 - < 2 cm	607	92,0	533	87,8	2,502	8,364	606	91,1	530	87,5	2,736	10,007
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	2,254	8,088	580	87,2	507	87,4	3,419	10,284
BASELINE	>= 2 - < 5 cm	1009	100,0	980	97,1	3,299	9,127	991	100,0	971	98,0	3,484	10,790
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	756	94,9	14,462	19,531	789	79,6	744	94,3	15,345	20,971
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	8,445	15,796	940	94,9	891	94,8	7,220	13,579
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	4,242	10,681	919	92,7	865	94,1	3,738	10,676
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	3,437	9,967	985	99,4	878	89,1	3,436	10,434

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	3,012	9,314	914	92,2	785	85,9	2,994	10,441
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	2,909	9,394	889	89,7	777	87,4	3,132	9,124
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	3,080	9,449	839	84,7	729	86,9	2,995	9,717
BASELINE	>= 5 cm	139	100,0	137	98,6	2,920	8,551	165	100,0	163	98,8	2,147	6,454
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	14,286	19,534	132	80,0	124	93,9	13,575	19,052
WEEK 13	>= 5 cm	130	93,5	125	96,2	8,533	16,067	152	92,1	140	92,1	5,952	12,172
WEEK 25	>= 5 cm	124	89,2	119	96,0	5,042	13,297	150	90,9	147	98,0	2,834	7,649
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	5,067	13,754	163	98,8	152	93,3	4,057	8,996
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	2,025	6,757	148	89,7	129	87,2	2,842	8,102
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	2,252	7,617	141	85,5	117	83,0	2,422	7,012
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	3,795	11,757	135	81,8	116	85,9	2,730	10,755
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	0,000	0,000
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	33,333	57,735	2	100,0	2	100,0	8,333	11,785
WEEK 13	Missing	3	100,0	3	100,0	33,333	57,735	2	100,0	2	100,0	0,000	0,000
WEEK 25	Missing	3	100,0	3	100,0	5,556	9,623	2	100,0	2	100,0	16,667	23,570
END OF TREATMENT	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 18	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	8,333	11,785
FU MONTH 24	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	3	100,0	3	100,0	16,667	28,868	2	100,0	2	100,0	0,000	0,000
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1321	98,1	2,650	7,980	1350	100,0	1314	97,3	3,184	9,833
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	13,725	18,829	1104	81,8	1044	94,6	14,783	20,045
WEEK 13	Yes	1308	97,1	1246	95,3	7,798	14,698	1324	98,1	1251	94,5	6,541	12,739
WEEK 25	Yes	1277	94,8	1227	96,1	3,966	10,369	1302	96,4	1229	94,4	3,634	10,437

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1214	90,1	3,611	10,264	1350	100,0	1238	91,7	3,110	9,641
FU MONTH 18	Yes	1291	95,8	1146	88,8	2,356	8,050	1298	96,1	1132	87,2	2,768	9,921
FU MONTH 24	Yes	1266	94,0	1109	87,6	2,750	9,216	1260	93,3	1091	86,6	2,734	8,767
FU MONTH 36	Yes	1219	90,5	1062	87,1	2,762	8,845	1195	88,5	1038	86,9	3,356	10,644
BASELINE	No	464	100,0	443	95,5	3,386	9,167	473	100,0	464	98,1	2,945	8,883
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	15,496	19,869	342	72,3	319	93,3	15,831	20,545
WEEK 13	No	380	81,9	361	95,0	8,587	16,106	401	84,8	388	96,8	7,388	12,786
WEEK 25	No	368	79,3	358	97,3	4,004	10,561	386	81,6	373	96,6	2,994	9,103
END OF TREATMENT	No	447	96,3	361	80,8	3,093	8,896	461	97,5	393	85,2	3,520	9,870
FU MONTH 18	No	372	80,2	340	91,4	2,745	8,136	390	82,5	344	88,2	2,955	9,185
FU MONTH 24	No	367	79,1	323	88,0	2,632	7,823	378	79,9	335	88,6	3,532	10,865
FU MONTH 36	No	352	75,9	330	93,8	3,131	10,410	361	76,3	316	87,5	2,373	7,547
Race													
BASELINE	White	1252	100,0	1208	96,5	2,787	8,144	1255	100,0	1217	97,0	2,999	9,263
END OF ANTHRACYCLINE	White	1010	80,7	934	92,5	12,866	18,182	1018	81,1	942	92,5	13,907	19,379
WEEK 13	White	1158	92,5	1086	93,8	7,305	14,729	1183	94,3	1099	92,9	6,309	12,056
WEEK 25	White	1120	89,5	1063	94,9	4,249	11,134	1150	91,6	1072	93,2	3,607	9,687
END OF TREATMENT	White	1238	98,9	1050	84,8	3,984	10,831	1244	99,1	1091	87,7	3,529	10,173
FU MONTH 18	White	1138	90,9	982	86,3	2,716	8,612	1152	91,8	967	83,9	3,051	10,069
FU MONTH 24	White	1115	89,1	942	84,5	2,955	9,680	1120	89,2	941	84,0	3,029	9,723
FU MONTH 36	White	1071	85,5	923	86,2	2,997	9,821	1064	84,8	901	84,7	3,311	10,503
BASELINE	Black	25	100,0	24	96,0	3,472	8,483	31	100,0	30	96,8	6,111	14,171
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	12,963	16,197	15	48,4	15	100,0	30,000	37,901
WEEK 13	Black	21	84,0	17	81,0	15,686	16,106	29	93,5	28	96,6	19,643	24,867

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	5,263	7,959	29	93,5	28	96,6	10,714	19,359
END OF TREATMENT	Black	24	96,0	22	91,7	5,303	9,465	31	100,0	28	90,3	7,143	16,623
FU MONTH 18	Black	23	92,0	17	73,9	2,941	8,810	29	93,5	24	82,8	8,333	24,077
FU MONTH 24	Black	22	88,0	18	81,8	2,778	6,391	28	90,3	23	82,1	3,623	8,641
FU MONTH 36	Black	22	88,0	18	81,8	6,481	11,630	26	83,9	20	76,9	10,833	23,740
BASELINE	Asian	477	100,0	475	99,6	2,807	8,679	484	100,0	480	99,2	3,403	10,217
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	17,128	20,782	375	77,5	368	98,1	17,482	21,116
WEEK 13	Asian	455	95,4	450	98,9	8,852	15,131	466	96,3	465	99,8	6,810	12,580
WEEK 25	Asian	450	94,3	449	99,8	3,267	8,724	465	96,1	459	98,7	2,651	9,390
END OF TREATMENT	Asian	475	99,6	452	95,2	2,176	6,900	484	100,0	464	95,9	2,047	6,480
FU MONTH 18	Asian	447	93,7	434	97,1	1,728	6,621	461	95,2	444	96,3	1,839	6,606
FU MONTH 24	Asian	442	92,7	423	95,7	2,128	6,937	445	91,9	421	94,6	2,534	8,144
FU MONTH 36	Asian	424	88,9	402	94,8	2,239	7,571	425	87,8	398	93,6	2,345	7,487
BASELINE	Other	52	100,0	52	100,0	4,167	8,654	51	100,0	50	98,0	1,667	7,715
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	15,789	21,205	36	70,6	36	100,0	13,889	16,183
WEEK 13	Other	49	94,2	49	100,0	12,245	18,564	45	88,2	45	100,0	8,519	16,136
WEEK 25	Other	49	94,2	49	100,0	3,741	9,170	42	82,4	41	97,6	4,878	17,177
END OF TREATMENT	Other	52	100,0	47	90,4	3,901	13,102	50	98,0	47	94,0	4,965	16,269
FU MONTH 18	Other	50	96,2	48	96,0	2,778	7,157	44	86,3	39	88,6	4,701	14,783
FU MONTH 24	Other	49	94,2	45	91,8	3,333	9,796	43	84,3	39	90,7	4,274	11,290
FU MONTH 36	Other	49	94,2	44	89,8	3,030	6,503	39	76,5	33	84,6	3,030	7,744
BASELINE	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	20,000	21,731	2	100,0	2	100,0	0,000	0,000
WEEK 13	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	8,333	11,785

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	6,667	9,129	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	8,333	16,667	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	4,167	8,333	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	10,000	22,361	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC02_SG.xls
11AUG2020 16:07

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Pain Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1763	97,3	19,219	21,259	1823	100,0	1778	97,5	20,285	22,163
END OF ANTHRACYCLINE	n/a	1432	79,1	1347	94,1	17,199	20,756	1446	79,3	1363	94,3	18,513	21,480
WEEK 13	n/a	1688	93,2	1608	95,3	20,947	23,353	1725	94,6	1639	95,0	23,805	24,367
WEEK 25	n/a	1645	90,8	1585	96,4	20,547	22,274	1688	92,6	1603	95,0	20,711	22,695
END OF TREATMENT	n/a	1794	99,1	1575	87,8	18,455	21,784	1811	99,3	1630	90,0	19,356	22,438
FU MONTH 18	n/a	1663	91,8	1486	89,4	18,013	22,156	1688	92,6	1478	87,6	19,159	23,151
FU MONTH 24	n/a	1633	90,2	1434	87,8	17,283	21,895	1638	89,9	1426	87,1	17,158	22,008
FU MONTH 36	n/a	1571	86,7	1392	88,6	15,733	22,172	1556	85,4	1355	87,1	16,458	21,593
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	17,687	21,084	43	100,0	40	93,0	19,167	24,620
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	10,753	17,506	26	60,5	25	96,2	21,333	25,694
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	14,394	16,702	40	93,0	39	97,5	23,932	25,591
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	16,667	18,898	38	88,4	35	92,1	23,333	25,629
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	18,939	21,743	42	97,7	37	88,1	18,018	23,033
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	20,930	23,029	39	90,7	36	92,3	24,537	26,573

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	15,116	16,987	39	90,7	34	87,2	16,176	21,899
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	13,704	16,395	39	90,7	37	94,9	16,216	17,781
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	16,336	20,585	278	100,0	271	97,5	17,159	19,557
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	14,804	16,934	203	73,0	191	94,1	20,244	24,007
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	18,723	22,683	263	94,6	253	96,2	23,913	25,721
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	17,717	20,657	256	92,1	247	96,5	20,040	22,185
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	16,593	21,411	276	99,3	255	92,4	18,824	22,929
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	16,591	20,303	259	93,2	233	90,0	18,455	23,781
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	15,391	20,307	256	92,1	230	89,8	13,478	20,116
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	14,419	22,183	251	90,3	227	90,4	14,684	20,794
BASELINE	1-3 positive nodes	907	100,0	885	97,6	19,492	21,098	900	100,0	878	97,6	20,273	22,221
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	665	93,3	16,692	21,008	707	78,6	668	94,5	18,338	20,390
WEEK 13	1-3 positive nodes	847	93,4	806	95,2	21,009	23,448	854	94,9	806	94,4	24,007	23,909
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	21,305	22,068	836	92,9	790	94,5	20,717	21,973
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	18,093	22,038	897	99,7	814	90,7	19,165	21,962
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	18,202	22,854	852	94,7	746	87,6	19,236	22,612

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	729	88,1	17,330	22,509	830	92,2	726	87,5	17,126	21,384
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	16,052	22,848	794	88,2	670	84,4	16,567	21,254
BASELINE	>= 4 positive nodes	596	100,0	577	96,8	20,191	21,742	602	100,0	589	97,8	21,817	22,917
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	19,244	21,717	510	84,7	479	93,9	17,919	21,686
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	22,403	23,862	568	94,4	541	95,2	23,444	24,370
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	21,019	23,453	558	92,7	531	95,2	20,841	23,810
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	19,770	21,545	596	99,0	524	87,9	20,006	22,930
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	18,110	21,830	538	89,4	463	86,1	18,970	23,431
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	18,286	22,002	513	85,2	436	85,0	19,228	23,742
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	16,081	21,584	472	78,4	421	89,2	17,260	22,836
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1403	97,5	18,912	21,065	1448	100,0	1413	97,6	20,099	21,688
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1345	94,1	17,224	20,761	1444	99,7	1362	94,3	18,514	21,488
WEEK 13	Anthracycline containing regimen	1347	93,6	1293	96,0	21,475	23,558	1374	94,9	1304	94,9	23,862	24,431
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	20,479	22,280	1346	93,0	1278	94,9	20,514	23,042
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1259	88,1	18,573	21,725	1444	99,7	1305	90,4	19,080	22,439

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1185	89,2	17,890	21,955	1340	92,5	1182	88,2	18,810	22,946
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1148	87,9	17,523	22,052	1308	90,3	1137	86,9	17,194	22,086
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	15,542	21,920	1244	85,9	1089	87,5	16,208	21,787
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	20,417	21,987	375	100,0	365	97,3	21,005	23,928
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	0,000	0,000	2	0,5	1	50,0	16,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	18,783	22,395	351	93,6	335	95,4	23,582	24,151
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	20,808	22,282	342	91,2	325	95,0	21,487	21,293
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	17,985	22,043	367	97,9	325	88,6	20,462	22,436
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	18,494	22,961	348	92,8	296	85,1	20,552	23,945
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	16,317	21,263	330	88,0	289	87,6	17,013	21,737
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	16,489	23,166	312	83,2	266	85,3	17,481	20,791
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	18,270	21,250	858	100,0	840	97,9	19,464	21,830
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	16,927	20,634	661	77,0	621	93,9	18,626	21,652
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	20,146	22,751	804	93,7	773	96,1	23,372	24,688
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	19,806	22,080	786	91,6	751	95,5	20,861	22,750
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	765	89,4	18,148	21,420	854	99,5	766	89,7	19,038	21,622
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	719	89,8	16,898	21,128	781	91,0	697	89,2	18,699	22,975
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	695	88,3	16,139	20,919	763	88,9	676	88,6	15,631	21,115
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	14,577	21,479	735	85,7	655	89,1	15,445	20,428
BASELINE	Positive (ER and/or PgR positive)	947	100,0	921	97,3	20,087	21,240	965	100,0	938	97,2	21,020	22,443
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	708	93,2	17,444	20,878	785	81,3	742	94,5	18,419	21,349
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	832	95,3	21,695	23,889	921	95,4	866	94,0	24,192	24,085
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	21,255	22,448	902	93,5	852	94,5	20,579	22,660
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	18,745	22,131	957	99,2	864	90,3	19,637	23,147
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	19,057	23,043	907	94,0	781	86,1	19,569	23,314
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	18,358	22,736	875	90,7	750	85,7	18,533	22,710

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	16,830	22,771	821	85,1	700	85,3	17,405	22,603
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	22,008	24,607	260	100,0	255	98,1	24,706	26,241
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	15,033	19,270	111	42,7	105	94,6	22,540	25,735
WEEK 13	USA/Canada	242	91,3	229	94,6	19,360	23,180	236	90,8	224	94,9	24,405	26,826
WEEK 25	USA/Canada	234	88,3	225	96,2	21,333	24,835	230	88,5	219	95,2	21,918	25,573
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	18,510	24,932	255	98,1	229	89,8	21,106	23,278
FU MONTH 18	USA/Canada	238	89,8	194	81,5	18,213	24,654	231	88,8	181	78,4	21,547	25,624
FU MONTH 24	USA/Canada	231	87,2	188	81,4	18,972	25,577	224	86,2	177	79,0	16,478	22,890
FU MONTH 36	USA/Canada	223	84,2	180	80,7	18,704	25,326	205	78,8	156	76,1	18,376	24,770
BASELINE	Western Europe	827	100,0	790	95,5	20,527	22,599	822	100,0	787	95,7	20,648	23,337
END OF ANTHRACYCLINE	Western Europe	732	88,5	669	91,4	17,688	22,268	728	88,6	664	91,2	18,725	23,120
WEEK 13	Western Europe	764	92,4	701	91,8	22,135	24,805	778	94,6	710	91,3	25,540	26,025
WEEK 25	Western Europe	738	89,2	693	93,9	22,968	24,497	750	91,2	682	90,9	21,994	24,440
END OF TREATMENT	Western Europe	821	99,3	694	84,5	21,206	23,820	817	99,4	705	86,3	21,277	25,369
FU MONTH 18	Western Europe	754	91,2	650	86,2	21,051	24,947	764	92,9	632	82,7	21,704	25,708
FU MONTH 24	Western Europe	739	89,4	614	83,1	20,385	24,902	747	90,9	620	83,0	19,140	24,617
FU MONTH 36	Western Europe	713	86,2	613	86,0	18,325	24,541	712	86,6	600	84,3	19,278	24,395
BASELINE	Asia Pacific	490	100,0	487	99,4	17,180	17,609	512	100,0	508	99,2	18,799	18,736
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	16,934	18,507	397	77,5	390	98,2	17,051	17,620
WEEK 13	Asia Pacific	466	95,1	465	99,8	21,685	21,937	493	96,3	492	99,8	21,477	20,475
WEEK 25	Asia Pacific	461	94,1	461	100,0	18,366	18,228	492	96,1	488	99,2	18,648	18,300

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	16,128	17,432	512	100,0	491	95,9	16,022	17,853
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	15,265	16,810	485	94,7	473	97,5	15,645	18,622
FU MONTH 24	Asia Pacific	454	92,7	442	97,4	13,386	15,550	470	91,8	448	95,3	14,807	18,018
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	12,360	17,771	453	88,5	432	95,4	12,269	15,852
BASELINE	Latin America	43	100,0	43	100,0	15,504	16,017	47	100,0	46	97,9	21,014	19,063
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	17,241	20,159	32	68,1	32	100,0	19,792	18,664
WEEK 13	Latin America	40	93,0	40	100,0	15,417	18,253	44	93,6	44	100,0	28,788	25,254
WEEK 25	Latin America	39	90,7	39	100,0	13,675	14,745	44	93,6	44	100,0	20,076	19,877
END OF TREATMENT	Latin America	42	97,7	38	90,5	14,912	20,427	45	95,7	42	93,3	20,238	18,601
FU MONTH 18	Latin America	41	95,3	37	90,2	15,315	20,555	42	89,4	40	95,2	16,667	21,350
FU MONTH 24	Latin America	40	93,0	36	90,0	12,037	17,188	41	87,2	39	95,1	15,812	17,913
FU MONTH 36	Latin America	38	88,4	34	89,5	12,745	16,442	37	78,7	36	97,3	14,815	14,788
BASELINE	Other	186	100,0	184	98,9	15,942	19,231	182	100,0	182	100,0	16,484	19,191
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	17,148	20,367	178	97,8	172	96,6	18,314	20,365
WEEK 13	Other	176	94,6	173	98,3	17,534	21,810	174	95,6	169	97,1	21,203	23,340
WEEK 25	Other	173	93,0	167	96,5	17,066	19,183	172	94,5	170	98,8	20,098	23,353
END OF TREATMENT	Other	185	99,5	162	87,6	14,095	17,969	182	100,0	163	89,6	18,405	19,912
FU MONTH 18	Other	171	91,9	153	89,5	13,617	18,579	166	91,2	152	91,6	17,325	20,469
FU MONTH 24	Other	169	90,9	154	91,1	15,260	18,568	156	85,7	142	91,0	17,136	20,718
FU MONTH 36	Other	160	86,0	147	91,9	11,565	17,837	149	81,9	131	87,9	15,522	19,741
Protocol version													
BASELINE	Protocol A	1240	100,0	1207	97,3	19,138	21,282	1246	100,0	1211	97,2	19,915	21,831

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	918	93,3	16,630	20,842	988	79,3	929	94,0	18,802	21,869
WEEK 13	Protocol A	1155	93,1	1109	96,0	20,153	23,493	1180	94,7	1114	94,4	23,414	24,608
WEEK 25	Protocol A	1125	90,7	1087	96,6	19,749	22,171	1157	92,9	1094	94,6	20,414	22,379
END OF TREATMENT	Protocol A	1229	99,1	1074	87,4	17,800	21,802	1236	99,2	1118	90,5	19,335	22,603
FU MONTH 18	Protocol A	1142	92,1	1026	89,8	17,853	22,462	1156	92,8	1007	87,1	18,868	22,998
FU MONTH 24	Protocol A	1124	90,6	996	88,6	17,436	22,354	1127	90,4	981	87,0	16,446	22,098
FU MONTH 36	Protocol A	1087	87,7	980	90,2	15,544	22,076	1069	85,8	937	87,7	15,973	21,485
BASELINE	Protocol Amendment B	571	100,0	556	97,4	19,394	21,225	577	100,0	567	98,3	21,076	22,855
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	18,415	20,544	458	79,4	434	94,8	17,896	20,633
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	22,712	22,963	545	94,5	525	96,3	24,635	23,850
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	22,289	22,420	531	92,0	509	95,9	21,349	23,370
END OF TREATMENT	Protocol Amendment B	565	98,9	501	88,7	19,860	21,700	575	99,7	512	89,0	19,401	22,097
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	18,370	21,477	532	92,2	471	88,5	19,781	23,489
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	16,933	20,834	511	88,6	445	87,1	18,727	21,751
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	16,181	22,419	487	84,4	418	85,8	17,544	21,822
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	16,556	20,638	321	100,0	311	96,9	17,417	20,244
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	14,206	17,038	229	71,3	216	94,3	20,370	24,148
WEEK 13	0 positive nodes	294	95,5	279	94,9	18,041	21,880	303	94,4	292	96,4	23,916	25,660
WEEK 25	0 positive nodes	287	93,2	281	97,9	17,556	20,369	294	91,6	282	95,9	20,449	22,617
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	16,974	21,443	318	99,1	292	91,8	18,721	22,904
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	17,300	20,789	298	92,8	269	90,3	19,269	24,209

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	15,344	19,749	295	91,9	264	89,5	13,826	20,330
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	14,295	21,268	290	90,3	264	91,0	14,899	20,374
BASELINE	>= 1 positive nodes	1503	100,0	1462	97,3	19,767	21,350	1502	100,0	1467	97,7	20,893	22,508
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1137	94,0	17,751	21,333	1217	81,0	1147	94,2	18,163	20,933
WEEK 13	>= 1 positive nodes	1394	92,7	1329	95,3	21,558	23,613	1422	94,7	1347	94,7	23,781	24,088
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	21,191	22,619	1394	92,8	1321	94,8	20,767	22,720
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1304	87,6	18,763	21,849	1493	99,4	1338	89,6	19,494	22,342
FU MONTH 18	>= 1 positive nodes	1371	91,2	1223	89,2	18,166	22,444	1390	92,5	1209	87,0	19,134	22,920
FU MONTH 24	>= 1 positive nodes	1343	89,4	1182	88,0	17,696	22,312	1343	89,4	1162	86,5	17,915	22,311
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	16,063	22,370	1266	84,3	1091	86,2	16,835	21,870
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	19,480	20,962	885	100,0	868	98,1	19,892	21,757
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	17,135	20,553	726	82,0	693	95,5	17,027	19,078
WEEK 13	Premenopausal	841	96,3	806	95,8	21,505	22,948	852	96,3	809	95,0	23,589	23,339
WEEK 25	Premenopausal	825	94,5	800	97,0	21,625	22,554	838	94,7	800	95,5	20,729	22,541
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	17,907	21,311	881	99,5	812	92,2	17,980	21,670
FU MONTH 18	Premenopausal	819	93,8	724	88,4	16,989	21,860	835	94,4	740	88,6	17,680	22,091
FU MONTH 24	Premenopausal	803	92,0	706	87,9	16,714	20,856	807	91,2	708	87,7	16,078	21,165

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	14,264	21,775	773	87,3	669	86,5	15,172	21,080
BASELINE	Postmenopausal	933	100,0	905	97,0	18,987	21,572	929	100,0	902	97,1	20,695	22,604
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	666	92,6	17,292	21,023	711	76,5	663	93,2	19,985	23,639
WEEK 13	Postmenopausal	842	90,2	798	94,8	20,426	23,787	864	93,0	822	95,1	23,966	25,330
WEEK 25	Postmenopausal	815	87,4	780	95,7	19,509	21,992	841	90,5	796	94,6	20,750	22,918
END OF TREATMENT	Postmenopausal	923	98,9	805	87,2	18,944	22,235	921	99,1	810	87,9	20,700	23,133
FU MONTH 18	Postmenopausal	839	89,9	759	90,5	18,972	22,443	844	90,9	730	86,5	20,685	24,142
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	17,887	22,902	823	88,6	713	86,6	18,186	22,685
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	17,133	22,502	776	83,5	680	87,6	17,794	22,072
BASELINE	Unknown/Missing	5	100,0	5	100,0	16,667	16,667	9	100,0	8	88,9	16,667	15,430
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	13,333	13,944	9	100,0	7	77,8	26,190	23,288
WEEK 13	Unknown/Missing	5	100,0	4	80,0	12,500	15,957	9	100,0	8	88,9	29,167	27,817
WEEK 25	Unknown/Missing	5	100,0	5	100,0	10,000	9,129	9	100,0	7	77,8	14,286	14,996
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	25,000	21,517	9	100,0	8	88,9	22,917	21,708
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	22,222	9,623	9	100,0	8	88,9	16,667	19,920
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	8,333	9,623	8	88,9	5	62,5	23,333	36,515
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	12,500	15,957	7	77,8	6	85,7	8,333	13,944
Age II													
BASELINE	< 65	1581	100,0	1543	97,6	19,529	21,346	1604	100,0	1570	97,9	20,085	21,823
END OF ANTHRACYCLINE	< 65	1268	80,2	1199	94,6	16,972	20,393	1287	80,2	1221	94,9	18,305	20,942
WEEK 13	< 65	1497	94,7	1428	95,4	20,787	23,026	1529	95,3	1455	95,2	23,872	24,214

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	20,742	22,144	1501	93,6	1430	95,3	20,723	22,409
END OF TREATMENT	< 65	1569	99,2	1386	88,3	18,182	21,208	1596	99,5	1447	90,7	19,178	22,129
FU MONTH 18	< 65	1474	93,2	1314	89,1	17,656	21,882	1497	93,3	1321	88,2	19,026	22,866
FU MONTH 24	< 65	1446	91,5	1264	87,4	17,049	21,585	1450	90,4	1270	87,6	16,693	21,552
FU MONTH 36	< 65	1390	87,9	1234	88,8	15,343	21,927	1383	86,2	1206	87,2	16,321	21,367
BASELINE	>= 65	230	100,0	220	95,7	17,045	20,548	219	100,0	208	95,0	21,795	24,582
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	19,032	23,491	159	72,6	142	89,3	20,305	25,660
WEEK 13	>= 65	191	83,0	180	94,2	22,222	25,832	196	89,5	184	93,9	23,279	25,609
WEEK 25	>= 65	181	78,7	178	98,3	19,007	23,285	187	85,4	173	92,5	20,617	25,009
END OF TREATMENT	>= 65	225	97,8	189	84,0	20,459	25,590	215	98,2	183	85,1	20,765	24,768
FU MONTH 18	>= 65	189	82,2	172	91,0	20,736	24,039	191	87,2	157	82,2	20,276	25,481
FU MONTH 24	>= 65	187	81,3	170	90,9	19,020	24,074	188	85,8	156	83,0	20,940	25,178
FU MONTH 36	>= 65	181	78,7	158	87,3	18,776	23,849	173	79,0	149	86,1	17,562	23,393
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	17,204	22,967	24	100,0	24	100,0	18,056	20,214
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	16,667	22,048	17	70,8	16	94,1	25,000	17,213
WEEK 13	Grade 1	31	96,9	30	96,8	28,333	29,082	23	95,8	22	95,7	23,485	19,693
WEEK 25	Grade 1	31	96,9	29	93,5	26,437	34,074	23	95,8	22	95,7	21,212	20,690
END OF TREATMENT	Grade 1	31	96,9	27	87,1	21,605	26,073	24	100,0	22	91,7	18,939	22,000
FU MONTH 18	Grade 1	30	93,8	27	90,0	26,543	29,330	23	95,8	22	95,7	21,970	18,819
FU MONTH 24	Grade 1	28	87,5	27	96,4	22,222	28,868	23	95,8	21	91,3	18,254	20,348
FU MONTH 36	Grade 1	27	84,4	26	96,3	21,795	33,918	22	91,7	20	90,9	19,167	18,157
BASELINE	Grade 2	552	100,0	537	97,3	18,467	20,102	557	100,0	543	97,5	19,337	21,679
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	17,374	20,838	446	80,1	424	95,1	18,278	21,117

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	19,856	23,316	524	94,1	504	96,2	23,743	23,770
WEEK 25	Grade 2	494	89,5	479	97,0	20,007	21,572	515	92,5	493	95,7	19,506	21,539
END OF TREATMENT	Grade 2	548	99,3	485	88,5	17,491	20,311	553	99,3	495	89,5	19,596	22,617
FU MONTH 18	Grade 2	507	91,8	457	90,1	17,214	22,220	517	92,8	448	86,7	18,118	22,623
FU MONTH 24	Grade 2	501	90,8	449	89,6	16,110	22,027	500	89,8	431	86,2	16,009	21,810
FU MONTH 36	Grade 2	487	88,2	438	89,9	14,193	20,842	476	85,5	415	87,2	15,904	21,981
BASELINE	Grade 3	1161	100,0	1132	97,5	19,773	21,646	1173	100,0	1143	97,4	20,735	22,455
END OF ANTHRACYCLINE	Grade 3	918	79,1	858	93,5	17,269	20,746	919	78,3	861	93,7	18,757	22,029
WEEK 13	Grade 3	1088	93,7	1031	94,8	21,209	23,099	1114	95,0	1053	94,5	23,884	24,764
WEEK 25	Grade 3	1059	91,2	1019	96,2	20,903	22,280	1087	92,7	1026	94,4	21,426	23,497
END OF TREATMENT	Grade 3	1150	99,1	1002	87,1	18,779	22,143	1165	99,3	1053	90,4	19,262	22,425
FU MONTH 18	Grade 3	1067	91,9	948	88,8	18,284	21,927	1085	92,5	949	87,5	19,442	23,406
FU MONTH 24	Grade 3	1046	90,1	904	86,4	17,920	21,658	1053	89,8	918	87,2	17,738	22,351
FU MONTH 36	Grade 3	1002	86,3	876	87,4	16,553	22,495	999	85,2	868	86,9	16,743	21,568
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	16,667	22,993	69	100,0	68	98,6	21,078	21,858
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	14,583	20,231	64	92,8	62	96,9	15,054	16,449
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	21,585	24,598	64	92,8	60	93,8	23,056	24,374
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	15,805	20,093	63	91,3	62	98,4	18,280	18,285
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	19,399	25,126	69	100,0	60	87,0	19,167	21,876
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	15,741	21,086	63	91,3	59	93,7	21,469	24,575

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	13,889	20,412	62	89,9	56	90,3	16,071	18,248
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	11,859	19,340	59	85,5	52	88,1	15,064	20,415
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	18,296	21,028	715	100,0	687	96,1	19,360	23,146
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	548	92,6	16,910	20,405	572	80,0	523	91,4	19,535	23,143
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	22,692	25,139	673	94,1	634	94,2	25,000	25,212
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	22,509	24,041	654	91,5	614	93,9	22,611	23,960
END OF TREATMENT	Breast conserving surgery	722	99,2	625	86,6	20,160	22,895	711	99,4	623	87,6	20,867	24,621
FU MONTH 18	Breast conserving surgery	678	93,1	596	87,9	20,246	23,555	659	92,2	561	85,1	20,410	23,693
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	19,329	23,502	644	90,1	555	86,2	17,477	22,299
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	16,548	23,401	616	86,2	538	87,3	17,472	22,385
BASELINE	Mastectomy	1083	100,0	1057	97,6	19,836	21,399	1107	100,0	1090	98,5	20,841	21,502
END OF ANTHRACYCLINE	Mastectomy	840	77,6	799	95,1	17,397	21,005	873	78,9	839	96,1	17,839	20,346
WEEK 13	Mastectomy	1011	93,4	969	95,8	19,797	22,034	1051	94,9	1004	95,5	23,074	23,802
WEEK 25	Mastectomy	980	90,5	946	96,5	19,221	20,905	1033	93,3	988	95,6	19,501	21,792
END OF TREATMENT	Mastectomy	1072	99,0	950	88,6	17,333	20,957	1099	99,3	1006	91,5	18,340	20,784
FU MONTH 18	Mastectomy	985	91,0	890	90,4	16,517	21,049	1028	92,9	916	89,1	18,304	22,645
FU MONTH 24	Mastectomy	967	89,3	858	88,7	15,909	20,647	993	89,7	870	87,6	16,935	21,837

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	15,181	21,295	939	84,8	817	87,0	15,789	21,043
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	18,992	21,072	665	100,0	642	96,5	18,692	21,438
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	15,804	20,052	523	78,6	493	94,3	19,574	21,790
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	19,720	22,232	631	94,9	606	96,0	23,185	23,825
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	19,840	21,315	617	92,8	588	95,3	20,295	21,426
END OF TREATMENT	0 - < 2 cm	655	99,2	579	88,4	17,933	20,897	661	99,4	598	90,5	19,259	22,172
FU MONTH 18	0 - < 2 cm	617	93,5	546	88,5	17,521	22,080	624	93,8	561	89,9	18,093	22,114
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	16,292	21,509	606	91,1	530	87,5	16,258	21,135
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	14,921	21,342	580	87,2	508	87,6	15,551	21,141
BASELINE	>= 2 - < 5 cm	1009	100,0	979	97,0	18,897	20,856	991	100,0	971	98,0	21,232	22,736
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	756	94,9	17,593	20,656	789	79,6	744	94,3	18,392	21,696
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	21,075	23,080	940	94,9	891	94,8	24,897	24,801
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	20,360	22,541	919	92,7	866	94,2	21,382	23,704
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	18,184	21,448	985	99,4	878	89,1	19,362	22,364

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	17,952	21,898	914	92,2	785	85,9	20,191	24,127
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	17,622	22,163	889	89,7	777	87,4	17,997	22,728
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	15,924	22,449	839	84,7	729	86,9	17,170	22,129
BASELINE	>= 5 cm	139	100,0	137	98,6	22,871	24,589	165	100,0	163	98,8	20,757	21,364
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	20,794	24,216	132	80,0	124	93,9	14,785	18,553
WEEK 13	>= 5 cm	130	93,5	125	96,2	25,600	29,295	152	92,1	140	92,1	19,524	23,650
WEEK 25	>= 5 cm	124	89,2	119	96,0	25,630	24,432	150	90,9	147	98,0	18,254	21,220
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	22,667	27,304	163	98,8	152	93,3	19,518	24,017
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	20,717	24,426	148	89,7	130	87,8	17,179	21,055
FU MONTH 24	>= 5 cm	118	84,9	112	94,9	19,643	21,944	141	85,5	117	83,0	15,242	20,596
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	17,987	23,884	135	81,8	116	85,9	15,517	19,748
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	33,333	0,000
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	16,667	16,667	2	100,0	2	100,0	33,333	0,000
WEEK 13	Missing	3	100,0	3	100,0	27,778	25,459	2	100,0	2	100,0	25,000	11,785
WEEK 25	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	33,333	47,140
END OF TREATMENT	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	33,333	23,570
FU MONTH 18	Missing	3	100,0	3	100,0	27,778	25,459	2	100,0	2	100,0	41,667	35,355
FU MONTH 24	Missing	3	100,0	3	100,0	16,667	16,667	2	100,0	2	100,0	41,667	35,355
FU MONTH 36	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	41,667	35,355
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1320	98,0	19,318	21,341	1350	100,0	1314	97,3	20,282	22,331
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	16,794	20,239	1104	81,8	1044	94,6	18,327	21,599
WEEK 13	Yes	1308	97,1	1246	95,3	21,429	24,022	1324	98,1	1251	94,5	23,661	24,498
WEEK 25	Yes	1277	94,8	1227	96,1	21,136	22,772	1302	96,4	1230	94,5	21,098	23,233

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1214	90,1	19,522	22,335	1350	100,0	1237	91,6	19,819	22,941
FU MONTH 18	Yes	1291	95,8	1146	88,8	18,834	22,623	1298	96,1	1134	87,4	19,283	23,087
FU MONTH 24	Yes	1266	94,0	1111	87,8	17,972	22,058	1260	93,3	1091	86,6	18,057	22,640
FU MONTH 36	Yes	1219	90,5	1062	87,1	16,290	22,603	1195	88,5	1039	86,9	16,971	21,939
BASELINE	No	464	100,0	443	95,5	18,924	21,032	473	100,0	464	98,1	20,295	21,702
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	18,618	22,454	342	72,3	319	93,3	19,122	21,108
WEEK 13	No	380	81,9	362	95,3	19,291	20,833	401	84,8	388	96,8	24,270	23,967
WEEK 25	No	368	79,3	358	97,3	18,529	20,375	386	81,6	373	96,6	19,437	20,805
END OF TREATMENT	No	447	96,3	361	80,8	14,866	19,420	461	97,5	393	85,2	17,897	20,737
FU MONTH 18	No	372	80,2	340	91,4	15,245	20,292	390	82,5	344	88,2	18,750	23,391
FU MONTH 24	No	367	79,1	323	88,0	14,912	21,188	378	79,9	335	88,6	14,229	19,556
FU MONTH 36	No	352	75,9	330	93,8	13,939	20,652	361	76,3	316	87,5	14,768	20,356
Race													
BASELINE	White	1252	100,0	1208	96,5	19,937	22,575	1255	100,0	1217	97,0	20,761	23,246
END OF ANTHRACYCLINE	White	1010	80,7	934	92,5	16,595	21,273	1018	81,1	942	92,5	18,454	22,613
WEEK 13	White	1158	92,5	1087	93,9	20,147	23,655	1183	94,3	1099	92,9	24,355	25,652
WEEK 25	White	1120	89,5	1063	94,9	21,292	23,588	1150	91,6	1073	93,3	21,311	24,262
END OF TREATMENT	White	1238	98,9	1050	84,8	19,143	23,121	1244	99,1	1090	87,6	20,550	24,247
FU MONTH 18	White	1138	90,9	982	86,3	18,975	23,781	1152	91,8	969	84,1	20,623	24,766
FU MONTH 24	White	1115	89,1	943	84,6	18,717	23,842	1120	89,2	941	84,0	18,278	23,932
FU MONTH 36	White	1071	85,5	923	86,2	17,208	23,793	1064	84,8	902	84,8	18,182	23,495
BASELINE	Black	25	100,0	24	96,0	25,694	19,021	31	100,0	30	96,8	31,667	32,563
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	12,963	13,889	15	48,4	15	100,0	27,778	26,478
WEEK 13	Black	21	84,0	17	81,0	23,529	28,903	29	93,5	28	96,6	33,929	29,911

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	22,807	29,508	29	93,5	28	96,6	30,952	27,108
END OF TREATMENT	Black	24	96,0	22	91,7	22,727	28,427	31	100,0	28	90,3	28,571	24,367
FU MONTH 18	Black	23	92,0	17	73,9	26,471	25,725	29	93,5	24	82,8	40,278	27,327
FU MONTH 24	Black	22	88,0	18	81,8	25,926	24,403	28	90,3	23	82,1	23,188	21,165
FU MONTH 36	Black	22	88,0	18	81,8	23,148	31,384	26	83,9	20	76,9	30,000	27,889
BASELINE	Asian	477	100,0	474	99,4	17,475	17,507	484	100,0	480	99,2	18,438	18,238
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	18,283	18,954	375	77,5	368	98,1	18,025	17,692
WEEK 13	Asian	455	95,4	450	98,9	22,926	22,268	466	96,3	465	99,8	22,043	20,640
WEEK 25	Asian	450	94,3	449	99,8	18,857	18,387	465	96,1	459	98,7	19,063	18,471
END OF TREATMENT	Asian	475	99,6	452	95,2	16,851	17,705	484	100,0	464	95,9	16,164	17,416
FU MONTH 18	Asian	447	93,7	434	97,1	15,438	16,908	461	95,2	444	96,3	15,428	18,101
FU MONTH 24	Asian	442	92,7	424	95,9	13,915	16,216	445	91,9	421	94,6	14,766	17,300
FU MONTH 36	Asian	424	88,9	402	94,8	12,065	16,402	425	87,8	398	93,6	12,395	15,779
BASELINE	Other	52	100,0	52	100,0	14,423	17,783	51	100,0	50	98,0	19,333	20,023
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	20,175	21,974	36	70,6	36	100,0	20,370	22,925
WEEK 13	Other	49	94,2	49	100,0	19,388	22,910	45	88,2	45	100,0	23,333	22,585
WEEK 25	Other	49	94,2	49	100,0	18,707	21,686	42	82,4	41	97,6	17,480	17,461
END OF TREATMENT	Other	52	100,0	47	90,4	15,957	21,127	50	98,0	47	94,0	18,085	17,662
FU MONTH 18	Other	50	96,2	48	96,0	17,014	23,941	44	86,3	39	88,6	13,248	19,564
FU MONTH 24	Other	49	94,2	45	91,8	15,556	21,438	43	84,3	39	90,7	13,248	16,745
FU MONTH 36	Other	49	94,2	44	89,8	14,394	23,181	39	76,5	33	84,6	11,111	13,608
BASELINE	Missing	5	100,0	5	100,0	30,000	41,500	2	100,0	1	50,0	33,333	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	36,667	38,006	2	100,0	2	100,0	33,333	47,140
WEEK 13	Missing	5	100,0	5	100,0	23,333	34,561	2	100,0	2	100,0	0,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	23,333	27,889	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	25,000	39,675	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	33,333	40,825	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	16,667	23,570	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	23,333	36,515	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC03_SG.xls
11AUG2020 16:09

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Dyspnea Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1760	97,2	6,723	15,275	1823	100,0	1775	97,4	8,394	17,383
END OF ANTHRACYCLINE	n/a	1432	79,1	1344	93,9	14,683	21,083	1446	79,3	1362	94,2	16,716	23,009
WEEK 13	n/a	1688	93,2	1602	94,9	18,664	24,040	1725	94,6	1638	95,0	22,405	25,645
WEEK 25	n/a	1645	90,8	1585	96,4	12,892	19,461	1688	92,6	1601	94,8	14,366	21,125
END OF TREATMENT	n/a	1794	99,1	1575	87,8	13,757	21,218	1811	99,3	1627	89,8	14,034	21,439
FU MONTH 18	n/a	1663	91,8	1484	89,2	12,713	19,741	1688	92,6	1474	87,3	13,297	20,432
FU MONTH 24	n/a	1633	90,2	1431	87,6	11,903	19,760	1638	89,9	1425	87,0	12,982	20,844
FU MONTH 36	n/a	1571	86,7	1392	88,6	11,375	19,843	1556	85,4	1349	86,7	13,047	20,328
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	4,082	11,040	43	100,0	40	93,0	5,000	14,222
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	17,204	22,560	26	60,5	25	96,2	17,333	29,059
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	14,729	22,185	40	93,0	39	97,5	20,513	22,446
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	10,078	15,490	38	88,4	35	92,1	20,952	26,918
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	8,333	14,601	42	97,7	37	88,1	14,414	18,493
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	7,937	14,369	39	90,7	36	92,3	16,667	24,560

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	7,752	15,998	39	90,7	34	87,2	12,745	23,232
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	4,444	13,484	39	90,7	37	94,9	11,712	17,944
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	5,952	14,723	278	100,0	271	97,5	6,765	16,460
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	16,292	22,754	203	73,0	191	94,1	16,928	23,413
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	234	94,4	21,225	27,286	263	94,6	253	96,2	23,847	23,711
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	13,165	20,641	256	92,1	247	96,5	12,551	19,707
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	13,803	20,691	276	99,3	252	91,3	12,963	21,854
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	10,909	19,171	259	93,2	232	89,6	12,931	18,750
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	208	85,2	11,058	20,476	256	92,1	230	89,8	12,899	20,729
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	10,233	20,091	251	90,3	227	90,4	13,216	19,370
BASELINE	1-3 positive nodes	907	100,0	884	97,5	6,900	15,508	900	100,0	876	97,3	8,752	17,875
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	663	93,0	13,675	20,088	707	78,6	667	94,3	16,992	22,546
WEEK 13	1-3 positive nodes	847	93,4	803	94,8	18,680	22,757	854	94,9	805	94,3	21,905	25,523
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	12,961	19,501	836	92,9	789	94,4	14,322	20,818
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	12,857	20,142	897	99,7	814	90,7	14,292	21,789
FU MONTH 18	1-3 positive nodes	838	92,4	737	87,9	12,709	19,730	852	94,7	744	87,3	12,993	20,278

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	11,692	19,621	830	92,2	726	87,5	13,039	20,526
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	11,678	19,643	794	88,2	664	83,6	12,500	20,289
BASELINE	>= 4 positive nodes	596	100,0	575	96,5	7,014	15,464	602	100,0	588	97,7	8,844	17,218
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	15,325	21,680	510	84,7	479	93,9	16,214	23,206
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	17,816	24,518	568	94,4	541	95,2	22,612	26,914
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	12,895	19,168	558	92,7	530	95,0	14,843	21,735
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	15,547	23,281	596	99,0	524	87,9	14,122	20,917
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	13,952	20,330	538	89,4	462	85,9	13,709	21,165
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	13,024	19,946	513	85,2	435	84,8	12,950	21,308
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	12,178	20,493	472	78,4	421	89,2	13,935	21,108
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1402	97,4	6,633	15,047	1448	100,0	1412	97,5	8,546	17,596
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1342	93,9	14,680	21,088	1444	99,7	1361	94,3	16,654	22,907
WEEK 13	Anthracycline containing regimen	1347	93,6	1290	95,8	18,398	23,543	1374	94,9	1303	94,8	22,180	25,502
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	12,894	19,275	1346	93,0	1276	94,8	14,394	21,104
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1259	88,1	13,768	21,620	1444	99,7	1303	90,2	13,738	21,341

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1183	89,0	12,651	19,741	1340	92,5	1179	88,0	12,723	20,004
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1145	87,7	11,674	19,626	1308	90,3	1136	86,9	13,322	21,417
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	11,401	19,860	1244	85,9	1083	87,1	12,712	20,204
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	7,076	16,156	375	100,0	363	96,8	7,805	16,537
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	100,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	312	91,5	19,765	26,006	351	93,6	335	95,4	23,284	26,213
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	12,883	20,196	342	91,2	325	95,0	14,256	21,240
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	13,713	19,565	367	97,9	324	88,3	15,226	21,819
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	12,957	19,769	348	92,8	295	84,8	15,593	21,946
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	12,821	20,299	330	88,0	289	87,6	11,649	18,395
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	11,269	19,809	312	83,2	266	85,3	14,411	20,810
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	6,730	14,972	858	100,0	839	97,8	8,304	17,038
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	637	94,8	16,013	22,236	661	77,0	621	93,9	18,035	23,425
WEEK 13	Negative (ER and PgR negative)	815	94,3	773	94,8	18,629	25,181	804	93,7	773	96,1	22,941	25,671
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	12,602	19,476	786	91,6	750	95,4	14,489	20,895
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	765	89,4	13,464	21,171	854	99,5	762	89,2	14,348	21,507
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	718	89,6	11,560	18,906	781	91,0	694	88,9	13,256	19,950
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	693	88,1	10,486	18,598	763	88,9	676	88,6	12,426	20,125
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	9,784	18,414	735	85,7	653	88,8	12,660	19,442
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	6,718	15,556	965	100,0	936	97,0	8,476	17,695
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	707	93,0	13,484	19,927	785	81,3	741	94,4	15,610	22,611
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	829	95,0	18,697	22,940	921	95,4	865	93,9	21,927	25,628
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	13,169	19,455	902	93,5	851	94,3	14,258	21,338
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	14,033	21,271	957	99,2	865	90,4	13,757	21,386
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	13,795	20,446	907	94,0	780	86,0	13,333	20,864
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	13,234	20,717	875	90,7	749	85,6	13,485	21,474

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	12,885	21,012	821	85,1	696	84,8	13,410	21,133
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	5,792	15,965	260	100,0	255	98,1	6,144	15,699
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	10,458	16,900	111	42,7	105	94,6	17,143	22,224
WEEK 13	USA/Canada	242	91,3	229	94,6	19,068	25,939	236	90,8	224	94,9	18,750	22,224
WEEK 25	USA/Canada	234	88,3	225	96,2	10,815	19,583	230	88,5	219	95,2	10,502	18,238
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	10,138	18,134	255	98,1	228	89,4	10,526	19,194
FU MONTH 18	USA/Canada	238	89,8	193	81,1	9,499	17,234	231	88,8	181	78,4	11,602	19,416
FU MONTH 24	USA/Canada	231	87,2	188	81,4	13,121	22,980	224	86,2	177	79,0	9,228	17,666
FU MONTH 36	USA/Canada	223	84,2	180	80,7	10,370	21,516	205	78,8	155	75,6	10,323	18,441
BASELINE	Western Europe	827	100,0	787	95,2	7,116	15,599	822	100,0	785	95,5	8,493	17,619
END OF ANTHRACYCLINE	Western Europe	732	88,5	666	91,0	16,717	23,069	728	88,6	663	91,1	18,552	25,042
WEEK 13	Western Europe	764	92,4	696	91,1	21,312	25,240	778	94,6	709	91,1	25,717	28,539
WEEK 25	Western Europe	738	89,2	693	93,9	14,478	20,754	750	91,2	680	90,7	16,127	23,232
END OF TREATMENT	Western Europe	821	99,3	694	84,5	16,763	23,941	817	99,4	703	86,0	16,216	24,122
FU MONTH 18	Western Europe	754	91,2	649	86,1	15,665	22,516	764	92,9	629	82,3	14,573	22,288
FU MONTH 24	Western Europe	739	89,4	612	82,8	13,889	21,439	747	90,9	619	82,9	14,917	23,032
FU MONTH 36	Western Europe	713	86,2	613	86,0	13,649	21,736	712	86,6	595	83,6	14,902	22,014
BASELINE	Asia Pacific	490	100,0	487	99,4	6,845	14,461	512	100,0	508	99,2	10,302	18,400
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	13,993	18,676	397	77,5	390	98,2	15,983	20,092
WEEK 13	Asia Pacific	466	95,1	464	99,6	17,098	21,904	493	96,3	492	99,8	21,409	22,667
WEEK 25	Asia Pacific	461	94,1	461	100,0	12,292	17,536	492	96,1	488	99,2	13,934	18,788

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	12,069	18,144	512	100,0	491	95,9	13,578	18,719
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	11,062	16,479	485	94,7	473	97,5	12,121	17,321
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	9,297	16,104	470	91,8	448	95,3	12,202	18,384
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	9,490	16,415	453	88,5	432	95,4	11,883	18,102
BASELINE	Latin America	43	100,0	43	100,0	2,326	8,592	47	100,0	46	97,9	3,623	10,490
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	5,747	12,814	32	68,1	32	100,0	5,208	12,297
WEEK 13	Latin America	40	93,0	40	100,0	10,833	19,078	44	93,6	44	100,0	11,364	15,983
WEEK 25	Latin America	39	90,7	39	100,0	5,128	12,184	44	93,6	44	100,0	3,788	10,701
END OF TREATMENT	Latin America	42	97,7	38	90,5	7,895	21,131	45	95,7	42	93,3	8,730	14,833
FU MONTH 18	Latin America	41	95,3	37	90,2	3,604	10,493	42	89,4	39	92,9	10,256	17,361
FU MONTH 24	Latin America	40	93,0	36	90,0	4,630	11,691	41	87,2	39	95,1	7,692	16,153
FU MONTH 36	Latin America	38	88,4	34	89,5	1,961	7,961	37	78,7	36	97,3	8,333	14,639
BASELINE	Other	186	100,0	184	98,9	7,065	16,108	182	100,0	181	99,5	6,998	16,485
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	12,331	20,384	178	97,8	172	96,6	13,178	22,093
WEEK 13	Other	176	94,6	173	98,3	13,487	21,518	174	95,6	169	97,1	19,132	25,371
WEEK 25	Other	173	93,0	167	96,5	12,575	19,573	172	94,5	170	98,8	16,275	22,715
END OF TREATMENT	Other	185	99,5	162	87,6	11,934	19,167	182	100,0	163	89,6	12,270	20,271
FU MONTH 18	Other	171	91,9	153	89,5	11,329	18,795	166	91,2	152	91,6	14,474	22,912
FU MONTH 24	Other	169	90,9	154	91,1	11,688	18,488	156	85,7	142	91,0	13,146	22,089
FU MONTH 36	Other	160	86,0	147	91,9	10,658	19,107	149	81,9	131	87,9	12,977	22,100
Protocol version													
BASELINE	Protocol A	1240	100,0	1207	97,3	6,656	15,444	1246	100,0	1209	97,0	8,382	17,411

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	916	93,1	15,211	21,573	988	79,3	929	94,0	17,546	24,162
WEEK 13	Protocol A	1155	93,1	1103	95,5	18,737	24,380	1180	94,7	1114	94,4	22,861	25,435
WEEK 25	Protocol A	1125	90,7	1087	96,6	12,450	19,413	1157	92,9	1093	94,5	14,456	21,073
END OF TREATMENT	Protocol A	1229	99,1	1074	87,4	13,718	21,299	1236	99,2	1114	90,1	13,585	21,359
FU MONTH 18	Protocol A	1142	92,1	1024	89,7	12,663	20,080	1156	92,8	1003	86,8	12,895	19,977
FU MONTH 24	Protocol A	1124	90,6	994	88,4	12,307	20,278	1127	90,4	980	87,0	12,857	20,882
FU MONTH 36	Protocol A	1087	87,7	980	90,2	11,259	20,247	1069	85,8	933	87,3	13,040	19,901
BASELINE	Protocol Amendment B	571	100,0	553	96,8	6,872	14,914	577	100,0	566	98,1	8,422	17,339
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	13,551	19,970	458	79,4	433	94,5	14,935	20,228
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	18,504	23,296	545	94,5	524	96,1	21,438	26,085
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	13,855	19,550	531	92,0	508	95,7	14,173	21,256
END OF TREATMENT	Protocol Amendment B	565	98,9	501	88,7	13,839	21,063	575	99,7	513	89,2	15,010	21,600
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	12,826	18,985	532	92,2	471	88,5	14,154	21,364
FU MONTH 24	Protocol Amendment B	509	89,1	437	85,9	10,984	18,517	511	88,6	445	87,1	13,258	20,783
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	11,650	18,867	487	84,4	416	85,4	13,061	21,280
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	5,648	14,189	321	100,0	311	96,9	6,538	16,179
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	16,427	22,674	229	71,3	216	94,3	16,975	24,057
WEEK 13	0 positive nodes	294	95,5	277	94,2	20,217	26,627	303	94,4	292	96,4	23,402	23,536
WEEK 25	0 positive nodes	287	93,2	281	97,9	12,693	19,946	294	91,6	282	95,9	13,593	20,865
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	12,915	19,909	318	99,1	289	90,9	13,149	21,430
FU MONTH 18	0 positive nodes	292	94,8	262	89,7	10,433	18,493	298	92,8	268	89,9	13,433	19,617

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	251	86,6	10,491	19,792	295	91,9	264	89,5	12,879	21,021
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	9,231	19,215	290	90,3	264	91,0	13,005	19,151
BASELINE	>= 1 positive nodes	1503	100,0	1459	97,1	6,945	15,485	1502	100,0	1464	97,5	8,789	17,608
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	14,361	20,771	1217	81,0	1146	94,2	16,667	22,817
WEEK 13	>= 1 positive nodes	1394	92,7	1325	95,1	18,340	23,462	1422	94,7	1346	94,7	22,189	26,083
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	12,935	19,363	1394	92,8	1319	94,6	14,531	21,184
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1304	87,6	13,931	21,483	1493	99,4	1338	89,6	14,225	21,444
FU MONTH 18	>= 1 positive nodes	1371	91,2	1222	89,1	13,202	19,971	1390	92,5	1206	86,8	13,267	20,616
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	12,203	19,749	1343	89,4	1161	86,4	13,006	20,813
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	11,867	19,960	1266	84,3	1085	85,7	13,057	20,613
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	6,839	15,283	885	100,0	866	97,9	7,429	16,266
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	13,314	19,800	726	82,0	693	95,5	14,478	20,599
WEEK 13	Premenopausal	841	96,3	804	95,6	17,952	23,165	852	96,3	809	95,0	21,838	24,452
WEEK 25	Premenopausal	825	94,5	800	97,0	13,042	19,539	838	94,7	798	95,2	13,367	19,675
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	13,229	20,642	881	99,5	812	92,2	12,562	20,229
FU MONTH 18	Premenopausal	819	93,8	723	88,3	11,480	19,027	835	94,4	738	88,4	11,066	18,198
FU MONTH 24	Premenopausal	803	92,0	705	87,8	10,544	18,738	807	91,2	707	87,6	11,410	19,401

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	9,807	18,534	773	87,3	668	86,4	11,826	19,698
BASELINE	Postmenopausal	933	100,0	902	96,7	6,652	15,310	929	100,0	901	97,0	9,175	18,181
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	663	92,2	16,088	22,272	711	76,5	662	93,1	18,933	24,886
WEEK 13	Postmenopausal	842	90,2	794	94,3	19,395	24,919	864	93,0	821	95,0	22,818	26,628
WEEK 25	Postmenopausal	815	87,4	780	95,7	12,778	19,419	841	90,5	796	94,6	15,285	22,419
END OF TREATMENT	Postmenopausal	923	98,9	805	87,2	14,244	21,772	921	99,1	807	87,6	15,489	22,485
FU MONTH 18	Postmenopausal	839	89,9	758	90,3	13,940	20,360	844	90,9	728	86,3	15,522	22,085
FU MONTH 24	Postmenopausal	825	88,4	722	87,5	13,296	20,665	823	88,6	713	86,6	14,446	22,033
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	12,867	20,928	776	83,5	676	87,1	14,152	20,813
BASELINE	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	8	88,9	25,000	29,547
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	13,333	18,257	9	100,0	7	77,8	28,571	40,500
WEEK 13	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	9	100,0	8	88,9	37,500	37,533
WEEK 25	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	23,810	25,198
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	9	100,0	8	88,9	16,667	25,198
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	9	100,0	8	88,9	16,667	35,635
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	8	88,9	5	62,5	26,667	27,889
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	7	77,8	5	71,4	26,667	27,889
Age II													
BASELINE	< 65	1581	100,0	1541	97,5	6,533	14,975	1604	100,0	1568	97,8	8,355	17,308
END OF ANTHRACYCLINE	< 65	1268	80,2	1196	94,3	14,409	20,580	1287	80,2	1221	94,9	16,680	22,689
WEEK 13	< 65	1497	94,7	1423	95,1	18,060	23,608	1529	95,3	1454	95,1	21,962	25,175

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	12,864	19,506	1501	93,6	1428	95,1	14,029	20,544
END OF TREATMENT	< 65	1569	99,2	1386	88,3	12,987	20,378	1596	99,5	1446	90,6	13,716	21,012
FU MONTH 18	< 65	1474	93,2	1313	89,1	12,211	19,277	1497	93,3	1318	88,0	12,898	20,011
FU MONTH 24	< 65	1446	91,5	1262	87,3	11,173	18,802	1450	90,4	1269	87,5	12,845	20,860
FU MONTH 36	< 65	1390	87,9	1234	88,8	10,778	19,315	1383	86,2	1202	86,9	12,729	20,307
BASELINE	>= 65	230	100,0	219	95,2	8,067	17,219	219	100,0	207	94,5	8,696	17,977
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	16,892	24,743	159	72,6	141	88,7	17,021	25,702
WEEK 13	>= 65	191	83,0	179	93,7	23,464	26,829	196	89,5	184	93,9	25,906	28,932
WEEK 25	>= 65	181	78,7	178	98,3	13,109	19,159	187	85,4	173	92,5	17,148	25,316
END OF TREATMENT	>= 65	225	97,8	189	84,0	19,400	25,954	215	98,2	181	84,2	16,575	24,501
FU MONTH 18	>= 65	189	82,2	171	90,5	16,569	22,687	191	87,2	156	81,7	16,667	23,494
FU MONTH 24	>= 65	187	81,3	169	90,4	17,357	25,221	188	85,8	156	83,0	14,103	20,752
FU MONTH 36	>= 65	181	78,7	158	87,3	16,034	23,107	173	79,0	147	85,0	15,646	20,387
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	9,677	19,614	24	100,0	24	100,0	11,111	18,822
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	13,725	26,507	17	70,8	16	94,1	20,833	29,502
WEEK 13	Grade 1	31	96,9	30	96,8	20,000	29,814	23	95,8	22	95,7	24,242	21,036
WEEK 25	Grade 1	31	96,9	29	93,5	14,943	24,537	23	95,8	22	95,7	12,121	24,224
END OF TREATMENT	Grade 1	31	96,9	27	87,1	13,580	21,202	24	100,0	22	91,7	18,182	22,366
FU MONTH 18	Grade 1	30	93,8	27	90,0	17,284	21,424	23	95,8	22	95,7	12,121	19,370
FU MONTH 24	Grade 1	28	87,5	27	96,4	18,519	26,688	23	95,8	21	91,3	23,810	33,571
FU MONTH 36	Grade 1	27	84,4	26	96,3	11,538	24,841	22	91,7	20	90,9	18,333	27,519
BASELINE	Grade 2	552	100,0	535	96,9	5,670	13,950	557	100,0	542	97,3	8,303	16,797
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	14,701	21,164	446	80,1	424	95,1	15,959	22,446

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	17,663	22,515	524	94,1	503	96,0	21,537	24,939
WEEK 25	Grade 2	494	89,5	479	97,0	12,665	19,094	515	92,5	493	95,7	14,740	20,473
END OF TREATMENT	Grade 2	548	99,3	485	88,5	13,471	21,147	553	99,3	494	89,3	14,980	21,030
FU MONTH 18	Grade 2	507	91,8	457	90,1	12,619	19,466	517	92,8	448	86,7	13,318	20,035
FU MONTH 24	Grade 2	501	90,8	448	89,4	12,798	20,311	500	89,8	430	86,0	12,713	20,322
FU MONTH 36	Grade 2	487	88,2	438	89,9	11,111	19,745	476	85,5	412	86,6	13,188	19,490
BASELINE	Grade 3	1161	100,0	1131	97,4	7,309	15,854	1173	100,0	1141	97,3	8,268	17,517
END OF ANTHRACYCLINE	Grade 3	918	79,1	855	93,1	14,776	21,125	919	78,3	860	93,6	16,860	23,224
WEEK 13	Grade 3	1088	93,7	1026	94,3	19,071	24,265	1114	95,0	1053	94,5	22,570	26,125
WEEK 25	Grade 3	1059	91,2	1019	96,2	13,117	19,354	1087	92,7	1024	94,2	14,323	21,382
END OF TREATMENT	Grade 3	1150	99,1	1002	87,1	14,138	21,248	1165	99,3	1051	90,2	13,511	21,512
FU MONTH 18	Grade 3	1067	91,9	946	88,7	12,720	19,854	1085	92,5	945	87,1	13,051	20,445
FU MONTH 24	Grade 3	1046	90,1	902	86,2	11,530	19,237	1053	89,8	918	87,2	12,818	20,806
FU MONTH 36	Grade 3	1002	86,3	876	87,4	11,492	19,514	999	85,2	865	86,6	12,640	20,526
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	3,704	12,139	69	100,0	68	98,6	10,294	19,323
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	13,194	17,851	64	92,8	62	96,9	18,817	22,276
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	19,126	28,841	64	92,8	60	93,8	26,111	24,619
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	9,770	21,637	63	91,3	62	98,4	12,903	21,215
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	9,836	21,382	69	100,0	60	87,0	13,889	23,201
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	11,111	19,426	63	91,3	59	93,7	17,514	23,453

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	7,407	19,063	62	89,9	56	90,3	13,690	18,831
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	11,538	23,694	59	85,5	52	88,1	16,667	20,346
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	705	96,8	5,957	15,048	715	100,0	686	95,9	7,386	16,226
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	546	92,2	14,957	21,610	572	80,0	523	91,4	17,272	23,461
WEEK 13	Breast conserving surgery	677	93,0	635	93,8	20,420	25,762	673	94,1	634	94,2	24,448	26,230
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	13,198	19,963	654	91,5	613	93,7	14,954	22,125
END OF TREATMENT	Breast conserving surgery	722	99,2	625	86,6	13,973	21,021	711	99,4	621	87,3	14,868	22,617
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	13,019	20,367	659	92,2	561	85,1	13,547	20,766
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	12,384	20,735	644	90,1	555	86,2	13,874	22,697
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	11,803	20,420	616	86,2	533	86,5	13,008	20,480
BASELINE	Mastectomy	1083	100,0	1055	97,4	7,235	15,411	1107	100,0	1088	98,3	9,038	18,058
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	14,495	20,725	873	78,9	838	96,0	16,348	22,737
WEEK 13	Mastectomy	1011	93,4	967	95,6	17,511	22,779	1051	94,9	1003	95,4	21,070	25,168
WEEK 25	Mastectomy	980	90,5	946	96,5	12,685	19,122	1033	93,3	987	95,5	13,948	20,424
END OF TREATMENT	Mastectomy	1072	99,0	950	88,6	13,614	21,356	1099	99,3	1005	91,4	13,433	20,501
FU MONTH 18	Mastectomy	985	91,0	890	90,4	12,509	19,320	1028	92,9	912	88,7	13,085	20,167
FU MONTH 24	Mastectomy	967	89,3	855	88,4	11,579	19,081	993	89,7	869	87,5	12,351	19,488

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	11,084	19,449	939	84,8	816	86,9	13,072	20,241
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	643	97,4	6,947	15,681	665	100,0	642	96,5	7,788	16,599
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	482	92,9	15,007	20,689	523	78,6	492	94,1	17,412	23,630
WEEK 13	0 - < 2 cm	620	93,9	580	93,5	19,425	24,115	631	94,9	606	96,0	22,662	25,494
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	12,636	18,906	617	92,8	588	95,3	15,023	21,295
END OF TREATMENT	0 - < 2 cm	655	99,2	579	88,4	13,702	20,479	661	99,4	598	90,5	14,214	21,058
FU MONTH 18	0 - < 2 cm	617	93,5	545	88,3	12,171	18,978	624	93,8	560	89,7	12,976	20,775
FU MONTH 24	0 - < 2 cm	607	92,0	532	87,6	12,469	20,177	606	91,1	529	87,3	13,296	20,964
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	11,365	19,426	580	87,2	506	87,2	12,516	19,715
BASELINE	>= 2 - < 5 cm	1009	100,0	978	96,9	6,544	15,093	991	100,0	969	97,8	8,738	17,651
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	754	94,6	14,279	20,992	789	79,6	744	94,3	16,487	23,073
WEEK 13	>= 2 - < 5 cm	935	92,7	894	95,6	17,934	23,510	940	94,9	890	94,7	22,659	25,876
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	12,917	19,631	919	92,7	864	94,0	13,696	20,896
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	13,249	21,236	985	99,4	875	88,8	13,714	21,567

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	829	89,8	13,189	20,205	914	92,2	783	85,7	13,793	20,366
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	11,677	19,440	889	89,7	777	87,4	12,827	21,066
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	11,009	19,870	839	84,7	726	86,5	13,269	20,714
BASELINE	>= 5 cm	139	100,0	137	98,6	7,056	14,814	165	100,0	162	98,2	8,436	18,318
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	16,190	23,622	132	80,0	124	93,9	15,323	20,117
WEEK 13	>= 5 cm	130	93,5	125	96,2	20,000	27,107	152	92,1	140	92,1	19,762	24,937
WEEK 25	>= 5 cm	124	89,2	119	96,0	13,725	20,998	150	90,9	147	98,0	15,193	20,729
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	17,600	24,162	163	98,8	152	93,3	14,912	21,967
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	11,526	20,012	148	89,7	129	87,2	11,628	19,388
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	10,811	20,182	141	85,5	117	83,0	12,251	18,361
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	14,191	21,780	135	81,8	115	85,2	13,913	20,701
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	33,333	47,140
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	16,667	23,570
WEEK 25	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	50,000	70,711
END OF TREATMENT	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	33,333	47,140
FU MONTH 18	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	16,667	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	33,333	47,140
FU MONTH 36	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	16,667	23,570
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1319	97,9	6,444	14,796	1350	100,0	1312	97,2	7,927	16,820
END OF ANTHRACYCLINE	Yes	1103	81,9	1045	94,7	14,928	21,253	1104	81,8	1044	94,6	16,284	22,633
WEEK 13	Yes	1308	97,1	1242	95,0	19,082	24,492	1324	98,1	1250	94,4	22,427	25,608
WEEK 25	Yes	1277	94,8	1227	96,1	13,230	19,642	1302	96,4	1228	94,3	14,522	21,489

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1214	90,1	14,690	21,892	1350	100,0	1236	91,6	14,132	21,375
FU MONTH 18	Yes	1291	95,8	1144	88,6	13,228	20,105	1298	96,1	1130	87,1	13,009	20,352
FU MONTH 24	Yes	1266	94,0	1109	87,6	12,444	20,263	1260	93,3	1090	86,5	12,844	20,950
FU MONTH 36	Yes	1219	90,5	1062	87,1	11,927	19,949	1195	88,5	1033	86,4	13,069	20,497
BASELINE	No	464	100,0	441	95,0	7,559	16,615	473	100,0	463	97,9	9,719	18,843
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	13,824	20,488	342	72,3	318	93,0	18,134	24,186
WEEK 13	No	380	81,9	360	94,7	17,222	22,385	401	84,8	388	96,8	22,337	25,796
WEEK 25	No	368	79,3	358	97,3	11,732	18,808	386	81,6	373	96,6	13,852	19,900
END OF TREATMENT	No	447	96,3	361	80,8	10,619	18,456	461	97,5	391	84,8	13,725	21,662
FU MONTH 18	No	372	80,2	340	91,4	10,980	18,383	390	82,5	344	88,2	14,244	20,693
FU MONTH 24	No	367	79,1	322	87,7	10,041	17,824	378	79,9	335	88,6	13,433	20,522
FU MONTH 36	No	352	75,9	330	93,8	9,596	19,418	361	76,3	316	87,5	12,975	19,798
Race													
BASELINE	White	1252	100,0	1204	96,2	6,645	15,501	1255	100,0	1214	96,7	7,770	17,041
END OF ANTHRACYCLINE	White	1010	80,7	931	92,2	15,217	21,942	1018	81,1	941	92,4	17,464	24,425
WEEK 13	White	1158	92,5	1082	93,4	19,501	24,765	1183	94,3	1098	92,8	23,983	27,259
WEEK 25	White	1120	89,5	1063	94,9	13,358	20,285	1150	91,6	1071	93,1	14,877	22,155
END OF TREATMENT	White	1238	98,9	1050	84,8	14,635	22,468	1244	99,1	1087	87,4	14,474	22,641
FU MONTH 18	White	1138	90,9	980	86,1	13,878	21,204	1152	91,8	966	83,9	14,113	22,039
FU MONTH 24	White	1115	89,1	941	84,4	13,284	21,348	1120	89,2	940	83,9	13,688	22,013
FU MONTH 36	White	1071	85,5	923	86,2	12,568	21,422	1064	84,8	896	84,2	13,876	21,540
BASELINE	Black	25	100,0	24	96,0	9,722	20,803	31	100,0	30	96,8	8,889	17,361
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	3,704	11,111	15	48,4	15	100,0	8,889	15,258
WEEK 13	Black	21	84,0	17	81,0	23,529	25,725	29	93,5	28	96,6	17,857	21,242

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	15,789	28,040	29	93,5	28	96,6	17,857	26,422
END OF TREATMENT	Black	24	96,0	22	91,7	22,727	27,958	31	100,0	28	90,3	20,238	24,578
FU MONTH 18	Black	23	92,0	17	73,9	13,725	20,612	29	93,5	24	82,8	16,667	21,979
FU MONTH 24	Black	22	88,0	18	81,8	18,519	28,520	28	90,3	23	82,1	13,043	19,434
FU MONTH 36	Black	22	88,0	18	81,8	14,815	26,127	26	83,9	20	76,9	10,000	15,672
BASELINE	Asian	477	100,0	475	99,6	7,158	14,852	484	100,0	480	99,2	10,417	18,599
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	14,035	18,922	375	77,5	368	98,1	15,942	19,826
WEEK 13	Asian	455	95,4	449	98,7	17,223	22,390	466	96,3	465	99,8	20,287	22,035
WEEK 25	Asian	450	94,3	449	99,8	12,324	17,440	465	96,1	459	98,7	13,943	18,670
END OF TREATMENT	Asian	475	99,6	452	95,2	11,947	17,892	484	100,0	464	95,9	13,218	18,527
FU MONTH 18	Asian	447	93,7	434	97,1	10,983	16,483	461	95,2	444	96,3	11,937	16,765
FU MONTH 24	Asian	442	92,7	423	95,7	9,220	15,277	445	91,9	421	94,6	12,193	18,664
FU MONTH 36	Asian	424	88,9	402	94,8	9,370	15,725	425	87,8	398	93,6	11,893	17,967
BASELINE	Other	52	100,0	52	100,0	3,846	10,753	51	100,0	50	98,0	4,000	10,942
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	10,526	19,149	36	70,6	36	100,0	9,259	15,142
WEEK 13	Other	49	94,2	49	100,0	12,925	21,318	45	88,2	45	100,0	9,630	15,279
WEEK 25	Other	49	94,2	49	100,0	8,163	14,483	42	82,4	41	97,6	4,065	11,043
END OF TREATMENT	Other	52	100,0	47	90,4	7,801	15,869	50	98,0	47	94,0	8,511	16,253
FU MONTH 18	Other	50	96,2	48	96,0	4,861	11,889	44	86,3	38	86,4	7,018	13,772
FU MONTH 24	Other	49	94,2	45	91,8	5,185	12,218	43	84,3	39	90,7	5,128	12,184
FU MONTH 36	Other	49	94,2	44	89,8	3,788	12,892	39	76,5	33	84,6	7,071	13,838
BASELINE	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	13,333	29,814	2	100,0	2	100,0	0,000	0,000
WEEK 13	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	8,333	16,667	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	16,667	33,333	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC04_SG.xls
11AUG2020 16:12

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Insomnia Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1761	97,2	24,948	27,010	1823	100,0	1774	97,3	27,039	28,364
END OF ANTHRACYCLINE	n/a	1432	79,1	1344	93,9	27,505	28,034	1446	79,3	1361	94,1	30,370	29,209
WEEK 13	n/a	1688	93,2	1606	95,1	31,341	29,017	1725	94,6	1635	94,8	31,723	29,238
WEEK 25	n/a	1645	90,8	1585	96,4	29,169	28,614	1688	92,6	1600	94,8	28,417	28,576
END OF TREATMENT	n/a	1794	99,1	1574	87,7	27,277	28,846	1811	99,3	1628	89,9	25,983	28,601
FU MONTH 18	n/a	1663	91,8	1485	89,3	24,759	27,928	1688	92,6	1475	87,4	26,531	28,633
FU MONTH 24	n/a	1633	90,2	1432	87,7	22,928	27,123	1638	89,9	1426	87,1	24,638	27,825
FU MONTH 36	n/a	1571	86,7	1392	88,6	23,827	28,260	1556	85,4	1352	86,9	25,148	28,281
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	17,007	25,570	43	100,0	39	90,7	30,769	26,912
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	26,882	30,331	26	60,5	25	96,2	41,333	35,066
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	30,303	27,673	40	93,0	39	97,5	35,043	29,567
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	20,930	27,239	38	88,4	35	92,1	37,143	30,002
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	24,242	28,178	42	97,7	37	88,1	28,829	26,249
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	17,054	21,047	39	90,7	36	92,3	23,148	28,530

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	13,953	19,562	39	90,7	34	87,2	32,353	28,996
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	14,815	19,534	39	90,7	37	94,9	21,622	22,521
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	251	97,7	24,701	26,847	278	100,0	271	97,5	23,985	26,191
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	23,464	27,518	203	73,0	191	94,1	30,541	29,879
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	234	94,4	30,199	29,129	263	94,6	253	96,2	31,225	29,620
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	27,731	29,313	256	92,1	247	96,5	25,371	26,959
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	30,103	29,571	276	99,3	255	92,4	24,706	27,022
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	23,333	26,670	259	93,2	231	89,2	25,974	28,636
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	23,285	26,353	256	92,1	230	89,8	24,058	29,072
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	21,705	28,354	251	90,3	227	90,4	23,789	26,084
BASELINE	1-3 positive nodes	907	100,0	885	97,6	25,574	27,048	900	100,0	876	97,3	28,615	29,047
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	662	92,8	28,651	28,344	707	78,6	668	94,5	30,090	28,590
WEEK 13	1-3 positive nodes	847	93,4	806	95,2	32,589	28,864	854	94,9	804	94,1	31,633	28,546
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	30,665	28,731	836	92,9	789	94,4	28,728	27,948
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	26,905	29,000	897	99,7	815	90,9	26,380	28,488
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	26,287	29,031	852	94,7	745	87,4	26,577	28,197

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	23,901	28,075	830	92,2	726	87,5	23,921	26,984
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	24,634	28,482	794	88,2	668	84,1	25,399	28,546
BASELINE	>= 4 positive nodes	596	100,0	576	96,6	24,769	27,097	602	100,0	588	97,7	25,850	28,275
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	27,472	27,578	510	84,7	477	93,5	30,119	29,450
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	30,013	29,310	568	94,4	539	94,9	31,849	30,108
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	28,240	28,109	558	92,7	529	94,8	28,796	30,018
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	26,859	28,349	596	99,0	521	87,4	25,784	29,716
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	23,760	27,178	538	89,4	463	86,1	26,998	29,395
FU MONTH 24	>= 4 positive nodes	516	86,6	452	87,6	22,050	26,415	513	85,2	436	85,0	25,535	28,417
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	24,512	28,485	472	78,4	420	89,0	25,794	29,470
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1402	97,4	24,869	27,065	1448	100,0	1410	97,4	26,052	27,668
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1342	93,9	27,521	28,044	1444	99,7	1360	94,2	30,343	29,203
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	31,115	29,165	1374	94,9	1302	94,8	31,260	29,427
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	29,256	29,015	1346	93,0	1276	94,8	28,553	28,693
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1258	88,0	27,213	28,464	1444	99,7	1303	90,2	26,145	28,777

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1184	89,1	24,747	27,928	1340	92,5	1180	88,1	26,412	28,636
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	23,298	27,142	1308	90,3	1137	86,9	24,626	27,857
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	23,342	27,964	1244	85,9	1086	87,3	24,831	28,196
BASELINE	Non-anthracycline containing regimen	372	100,0	359	96,5	25,255	26,829	375	100,0	364	97,1	30,861	30,654
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	32,272	28,430	351	93,6	333	94,9	33,534	28,458
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	28,834	27,052	342	91,2	324	94,7	27,881	28,148
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	27,532	30,367	367	97,9	325	88,6	25,333	27,918
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	24,806	27,975	348	92,8	295	84,8	27,006	28,662
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	21,445	27,046	330	88,0	289	87,6	24,683	27,746
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	25,741	29,373	312	83,2	266	85,3	26,441	28,640
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	841	97,3	24,534	27,007	858	100,0	838	97,7	26,492	27,765
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	26,500	28,431	661	77,0	619	93,6	31,718	30,768
WEEK 13	Negative (ER and PgR negative)	815	94,3	775	95,1	29,376	28,682	804	93,7	773	96,1	31,048	29,125
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	27,742	28,358	786	91,6	750	95,4	27,422	28,340
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	26,920	28,371	854	99,5	765	89,6	25,403	27,886
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	718	89,6	22,331	26,312	781	91,0	694	88,9	26,225	28,942
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	20,893	25,462	763	88,9	676	88,6	24,063	27,509
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	22,370	27,645	735	85,7	654	89,0	24,261	27,286
BASELINE	Positive (ER and/or PgR positive)	947	100,0	920	97,1	25,326	27,021	965	100,0	936	97,0	27,528	28,896
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	705	92,8	28,416	27,657	785	81,3	742	94,5	29,245	27,812
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	33,173	29,224	921	95,4	862	93,6	32,328	29,343
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	30,535	28,809	902	93,5	850	94,2	29,294	28,771
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	27,613	29,302	957	99,2	863	90,2	26,497	29,227
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	27,032	29,194	907	94,0	781	86,1	26,803	28,370
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	24,842	28,483	875	90,7	750	85,7	25,156	28,115

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	25,210	28,782	821	85,1	698	85,0	25,979	29,177
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	28,571	26,062	260	100,0	254	97,7	32,283	31,207
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	33,333	28,144	111	42,7	105	94,6	34,921	29,736
WEEK 13	USA/Canada	242	91,3	227	93,8	35,389	27,795	236	90,8	223	94,5	36,771	30,398
WEEK 25	USA/Canada	234	88,3	225	96,2	32,593	28,425	230	88,5	219	95,2	29,376	28,816
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	30,415	30,373	255	98,1	229	89,8	26,638	28,163
FU MONTH 18	USA/Canada	238	89,8	194	81,5	29,038	29,560	231	88,8	181	78,4	29,834	31,526
FU MONTH 24	USA/Canada	231	87,2	188	81,4	25,709	28,756	224	86,2	177	79,0	24,670	28,872
FU MONTH 36	USA/Canada	223	84,2	180	80,7	25,741	29,654	205	78,8	156	76,1	29,701	30,661
BASELINE	Western Europe	827	100,0	788	95,3	27,961	28,825	822	100,0	785	95,5	30,616	29,757
END OF ANTHRACYCLINE	Western Europe	732	88,5	666	91,0	29,580	30,164	728	88,6	662	90,9	33,434	31,008
WEEK 13	Western Europe	764	92,4	701	91,8	34,712	31,214	778	94,6	707	90,9	35,408	31,319
WEEK 25	Western Europe	738	89,2	693	93,9	33,045	31,703	750	91,2	679	90,5	33,775	31,065
END OF TREATMENT	Western Europe	821	99,3	693	84,4	31,987	30,957	817	99,4	704	86,2	31,061	31,922
FU MONTH 18	Western Europe	754	91,2	649	86,1	29,019	30,741	764	92,9	630	82,5	31,693	30,293
FU MONTH 24	Western Europe	739	89,4	613	82,9	27,080	29,748	747	90,9	620	83,0	29,462	30,186
FU MONTH 36	Western Europe	713	86,2	613	86,0	27,406	30,950	712	86,6	597	83,8	28,141	29,617
BASELINE	Asia Pacific	490	100,0	487	99,4	19,302	24,693	512	100,0	508	99,2	20,407	24,798
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	24,242	25,610	397	77,5	390	98,2	26,154	26,610
WEEK 13	Asia Pacific	466	95,1	465	99,8	26,738	25,977	493	96,3	492	99,8	26,084	25,694
WEEK 25	Asia Pacific	461	94,1	461	100,0	22,849	23,436	492	96,1	488	99,2	21,858	24,270

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	20,402	24,404	512	100,0	491	95,9	20,570	24,188
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	18,142	22,534	485	94,7	473	97,5	19,521	24,005
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	16,100	21,563	470	91,8	448	95,3	17,783	22,491
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	18,740	23,705	453	88,5	432	95,4	19,676	25,002
BASELINE	Latin America	43	100,0	43	100,0	19,380	22,102	47	100,0	46	97,9	32,609	26,749
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	24,138	25,034	32	68,1	32	100,0	33,333	28,081
WEEK 13	Latin America	40	93,0	40	100,0	20,000	21,082	44	93,6	44	100,0	31,061	27,278
WEEK 25	Latin America	39	90,7	39	100,0	18,803	23,933	44	93,6	44	100,0	23,485	26,491
END OF TREATMENT	Latin America	42	97,7	38	90,5	16,667	22,924	45	95,7	42	93,3	21,429	21,866
FU MONTH 18	Latin America	41	95,3	37	90,2	10,811	17,663	42	89,4	39	92,9	28,205	31,099
FU MONTH 24	Latin America	40	93,0	36	90,0	10,185	19,222	41	87,2	39	95,1	25,641	28,058
FU MONTH 36	Latin America	38	88,4	34	89,5	11,765	19,903	37	78,7	36	97,3	22,222	22,537
BASELINE	Other	186	100,0	184	98,9	23,188	24,512	182	100,0	181	99,5	21,363	22,995
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	23,699	23,508	178	97,8	172	96,6	24,806	25,585
WEEK 13	Other	176	94,6	173	98,3	27,360	28,009	174	95,6	169	97,1	26,233	25,241
WEEK 25	Other	173	93,0	167	96,5	28,343	25,775	172	94,5	170	98,8	25,882	25,578
END OF TREATMENT	Other	185	99,5	162	87,6	25,103	25,756	182	100,0	162	89,0	20,576	23,537
FU MONTH 18	Other	171	91,9	153	89,5	24,183	24,849	166	91,2	152	91,6	22,588	25,620
FU MONTH 24	Other	169	90,9	154	91,1	25,541	25,506	156	85,7	142	91,0	24,883	26,760
FU MONTH 36	Other	160	86,0	147	91,9	23,810	25,583	149	81,9	131	87,9	24,936	28,146
Protocol version													
BASELINE	Protocol A	1240	100,0	1207	97,3	25,380	27,306	1246	100,0	1209	97,0	27,406	28,366

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	917	93,2	26,463	27,513	988	79,3	927	93,8	31,140	29,858
WEEK 13	Protocol A	1155	93,1	1107	95,8	30,985	28,780	1180	94,7	1111	94,2	32,253	29,626
WEEK 25	Protocol A	1125	90,7	1087	96,6	28,212	28,490	1157	92,9	1091	94,3	28,323	28,509
END OF TREATMENT	Protocol A	1229	99,1	1074	87,4	26,785	29,025	1236	99,2	1116	90,3	26,792	29,070
FU MONTH 18	Protocol A	1142	92,1	1025	89,8	24,260	27,933	1156	92,8	1004	86,9	26,527	28,731
FU MONTH 24	Protocol A	1124	90,6	994	88,4	22,971	27,400	1127	90,4	981	87,0	25,144	28,328
FU MONTH 36	Protocol A	1087	87,7	980	90,2	23,707	29,083	1069	85,8	936	87,6	25,214	28,269
BASELINE	Protocol Amendment B	571	100,0	554	97,0	24,007	26,353	577	100,0	565	97,9	26,254	28,369
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	427	95,3	29,742	29,027	458	79,4	434	94,8	28,725	27,732
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	32,131	29,549	545	94,5	524	96,1	30,598	28,393
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	31,258	28,802	531	92,0	509	95,9	28,618	28,747
END OF TREATMENT	Protocol Amendment B	565	98,9	500	88,5	28,333	28,460	575	99,7	512	89,0	24,219	27,497
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	25,870	27,916	532	92,2	471	88,5	26,539	28,452
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	22,831	26,516	511	88,6	445	87,1	23,521	26,680
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	24,110	26,228	487	84,4	416	85,4	25,000	28,341
Nodal status													
BASELINE	0 positive nodes	308	100,0	300	97,4	23,444	26,753	321	100,0	310	96,6	24,839	26,335
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	23,968	27,900	229	71,3	216	94,3	31,790	30,630
WEEK 13	0 positive nodes	294	95,5	278	94,6	30,216	28,855	303	94,4	292	96,4	31,735	29,591
WEEK 25	0 positive nodes	287	93,2	281	97,9	26,690	29,062	294	91,6	282	95,9	26,832	27,573
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	29,151	29,379	318	99,1	292	91,8	25,228	26,916
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	22,307	25,904	298	92,8	267	89,6	25,593	28,584

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	21,693	25,533	295	91,9	264	89,5	25,126	29,140
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	20,513	27,127	290	90,3	264	91,0	23,485	25,586
BASELINE	>= 1 positive nodes	1503	100,0	1461	97,2	25,257	27,061	1502	100,0	1464	97,5	27,505	28,762
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1134	93,8	28,160	28,022	1217	81,0	1145	94,1	30,102	28,939
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	31,576	29,056	1422	94,7	1343	94,4	31,720	29,172
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	29,703	28,500	1394	92,8	1318	94,5	28,756	28,785
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1303	87,5	26,887	28,731	1493	99,4	1336	89,5	26,148	28,963
FU MONTH 18	>= 1 positive nodes	1371	91,2	1222	89,1	25,286	28,327	1390	92,5	1208	86,9	26,738	28,651
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	23,192	27,454	1343	89,4	1162	86,5	24,527	27,529
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	24,588	28,470	1266	84,3	1088	85,9	25,551	28,893
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	854	97,8	22,756	25,901	885	100,0	865	97,7	25,125	27,465
END OF ANTHRACYCLINE	Premenopausal	708	81,1	674	95,2	26,756	28,173	726	82,0	692	95,3	29,721	28,605
WEEK 13	Premenopausal	841	96,3	805	95,7	34,120	30,305	852	96,3	809	95,0	32,674	29,473
WEEK 25	Premenopausal	825	94,5	800	97,0	31,167	29,235	838	94,7	799	95,3	29,954	29,495
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	25,805	28,313	881	99,5	810	91,9	25,802	29,267
FU MONTH 18	Premenopausal	819	93,8	724	88,4	23,573	27,607	835	94,4	740	88,6	25,631	28,533
FU MONTH 24	Premenopausal	803	92,0	705	87,8	22,695	27,328	807	91,2	708	87,7	22,599	27,079

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	22,338	27,959	773	87,3	669	86,5	23,468	28,473
BASELINE	Postmenopausal	933	100,0	902	96,7	27,088	27,903	929	100,0	901	97,0	28,783	29,064
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	665	92,5	28,271	27,914	711	76,5	662	93,1	30,967	29,782
WEEK 13	Postmenopausal	842	90,2	797	94,7	28,565	27,447	864	93,0	818	94,7	30,725	29,014
WEEK 25	Postmenopausal	815	87,4	780	95,7	27,222	27,875	841	90,5	794	94,4	26,868	27,612
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	28,690	29,346	921	99,1	810	87,9	26,132	28,009
FU MONTH 18	Postmenopausal	839	89,9	758	90,3	25,814	28,216	844	90,9	727	86,1	27,419	28,698
FU MONTH 24	Postmenopausal	825	88,4	723	87,6	23,190	26,982	823	88,6	713	86,6	26,695	28,424
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	25,221	28,546	776	83,5	677	87,2	26,637	27,814
BASELINE	Unknown/Missing	5	100,0	5	100,0	13,333	18,257	9	100,0	8	88,9	37,500	33,034
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	26,667	27,889	9	100,0	7	77,8	38,095	35,635
WEEK 13	Unknown/Missing	5	100,0	4	80,0	25,000	16,667	9	100,0	8	88,9	37,500	27,817
WEEK 25	Unknown/Missing	5	100,0	5	100,0	13,333	18,257	9	100,0	7	77,8	28,571	23,002
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	25,000	16,667	9	100,0	8	88,9	29,167	21,362
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	44,444	19,245	9	100,0	8	88,9	29,167	33,034
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	8	88,9	5	62,5	20,000	29,814
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	25,000	16,667	7	77,8	6	85,7	44,444	45,542
Age II													
BASELINE	< 65	1581	100,0	1542	97,5	24,968	27,011	1604	100,0	1566	97,6	26,650	27,934
END OF ANTHRACYCLINE	< 65	1268	80,2	1196	94,3	27,564	28,033	1287	80,2	1219	94,7	30,407	28,932
WEEK 13	< 65	1497	94,7	1426	95,3	31,533	29,084	1529	95,3	1453	95,0	31,842	29,172

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	29,874	28,763	1501	93,6	1428	95,1	28,711	28,491
END OF TREATMENT	< 65	1569	99,2	1385	88,3	26,955	28,480	1596	99,5	1445	90,5	26,090	28,984
FU MONTH 18	< 65	1474	93,2	1313	89,1	24,575	27,888	1497	93,3	1318	88,0	26,277	28,665
FU MONTH 24	< 65	1446	91,5	1263	87,3	22,697	27,007	1450	90,4	1270	87,6	24,541	27,768
FU MONTH 36	< 65	1390	87,9	1234	88,8	23,555	27,997	1383	86,2	1205	87,1	25,090	28,307
BASELINE	>= 65	230	100,0	219	95,2	24,810	27,061	219	100,0	208	95,0	29,968	31,331
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	27,027	28,132	159	72,6	142	89,3	30,047	31,588
WEEK 13	>= 65	191	83,0	180	94,2	29,815	28,515	196	89,5	182	92,9	30,769	29,827
WEEK 25	>= 65	181	78,7	178	98,3	23,596	26,846	187	85,4	172	92,0	25,969	29,243
END OF TREATMENT	>= 65	225	97,8	189	84,0	29,630	31,385	215	98,2	183	85,1	25,137	25,431
FU MONTH 18	>= 65	189	82,2	172	91,0	26,163	28,275	191	87,2	157	82,2	28,662	28,359
FU MONTH 24	>= 65	187	81,3	169	90,4	24,655	28,000	188	85,8	156	83,0	25,427	28,363
FU MONTH 36	>= 65	181	78,7	158	87,3	25,949	30,244	173	79,0	147	85,0	25,624	28,152
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	34,409	30,409	24	100,0	24	100,0	25,000	22,522
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	33,333	28,868	17	70,8	16	94,1	29,167	31,914
WEEK 13	Grade 1	31	96,9	30	96,8	41,111	29,921	23	95,8	22	95,7	31,818	26,181
WEEK 25	Grade 1	31	96,9	29	93,5	42,529	34,384	23	95,8	22	95,7	21,212	21,932
END OF TREATMENT	Grade 1	31	96,9	27	87,1	28,395	30,246	24	100,0	22	91,7	22,727	25,996
FU MONTH 18	Grade 1	30	93,8	26	86,7	33,333	35,277	23	95,8	22	95,7	28,788	31,363
FU MONTH 24	Grade 1	28	87,5	27	96,4	28,395	31,628	23	95,8	21	91,3	19,048	24,881
FU MONTH 36	Grade 1	27	84,4	26	96,3	28,205	32,238	22	91,7	20	90,9	25,000	23,878
BASELINE	Grade 2	552	100,0	537	97,3	21,664	25,520	557	100,0	542	97,3	25,277	27,542
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	25,217	25,958	446	80,1	424	95,1	30,582	30,065

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	27,778	27,391	524	94,1	502	95,8	31,275	28,220
WEEK 25	Grade 2	494	89,5	479	97,0	26,166	28,230	515	92,5	492	95,5	27,710	28,263
END OF TREATMENT	Grade 2	548	99,3	485	88,5	24,467	27,636	553	99,3	496	89,7	24,866	27,134
FU MONTH 18	Grade 2	507	91,8	457	90,1	22,028	25,953	517	92,8	448	86,7	24,926	28,835
FU MONTH 24	Grade 2	501	90,8	448	89,4	21,801	27,004	500	89,8	431	86,2	23,743	27,764
FU MONTH 36	Grade 2	487	88,2	438	89,9	22,603	27,229	476	85,5	413	86,8	23,487	27,379
BASELINE	Grade 3	1161	100,0	1130	97,3	26,254	27,439	1173	100,0	1140	97,2	28,363	28,975
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	28,699	29,119	919	78,3	859	93,5	30,889	29,155
WEEK 13	Grade 3	1088	93,7	1029	94,6	32,847	29,603	1114	95,0	1051	94,3	32,699	30,055
WEEK 25	Grade 3	1059	91,2	1019	96,2	30,357	28,475	1087	92,7	1024	94,2	29,557	29,048
END OF TREATMENT	Grade 3	1150	99,1	1001	87,0	28,738	29,344	1165	99,3	1050	90,1	26,667	29,363
FU MONTH 18	Grade 3	1067	91,9	948	88,8	26,090	28,561	1085	92,5	946	87,2	27,449	28,390
FU MONTH 24	Grade 3	1046	90,1	903	86,3	23,477	27,188	1053	89,8	918	87,2	25,744	28,181
FU MONTH 36	Grade 3	1002	86,3	876	87,4	24,772	28,756	999	85,2	868	86,9	26,344	29,080
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	24,868	27,414	69	100,0	68	98,6	19,608	24,593
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	24,306	24,543	64	92,8	62	96,9	22,043	21,715
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	29,508	28,609	64	92,8	60	93,8	18,333	19,816
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	26,437	28,448	63	91,3	62	98,4	17,742	22,355
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	25,137	28,321	69	100,0	60	87,0	24,444	28,035
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	20,370	27,023	63	91,3	59	93,7	23,164	29,849

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	20,370	24,586	62	89,9	56	90,3	15,476	21,048
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	16,026	25,127	59	85,5	51	86,4	18,301	21,410
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	26,582	27,333	715	100,0	686	95,9	26,822	28,417
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	545	92,1	28,869	29,192	572	80,0	521	91,1	31,222	29,559
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	33,698	29,595	673	94,1	632	93,9	34,019	30,223
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	32,238	30,390	654	91,5	612	93,6	29,902	29,375
END OF TREATMENT	Breast conserving surgery	722	99,2	624	86,4	30,235	30,059	711	99,4	622	87,5	28,349	29,763
FU MONTH 18	Breast conserving surgery	678	93,1	595	87,8	27,451	29,349	659	92,2	561	85,1	29,352	28,626
FU MONTH 24	Breast conserving surgery	666	91,5	575	86,3	25,971	28,681	644	90,1	555	86,2	26,246	28,214
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	25,919	30,026	616	86,2	535	86,9	26,168	28,277
BASELINE	Mastectomy	1083	100,0	1055	97,4	23,855	26,748	1107	100,0	1087	98,2	27,139	28,330
END OF ANTHRACYCLINE	Mastectomy	840	77,6	799	95,1	26,575	27,195	873	78,9	839	96,1	29,797	28,983
WEEK 13	Mastectomy	1011	93,4	967	95,6	29,783	28,537	1051	94,9	1002	95,3	30,273	28,535
WEEK 25	Mastectomy	980	90,5	946	96,5	27,097	27,171	1033	93,3	987	95,5	27,491	28,059
END OF TREATMENT	Mastectomy	1072	99,0	950	88,6	25,333	27,867	1099	99,3	1005	91,4	24,444	27,684
FU MONTH 18	Mastectomy	985	91,0	890	90,4	22,959	26,803	1028	92,9	913	88,8	24,717	28,421
FU MONTH 24	Mastectomy	967	89,3	857	88,6	20,887	25,843	993	89,7	870	87,6	23,602	27,555

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	22,410	26,924	939	84,8	817	87,0	24,480	28,281
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	24,599	26,878	665	100,0	640	96,2	26,615	28,066
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	481	92,7	27,928	27,189	523	78,6	492	94,1	32,317	30,331
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	32,135	28,098	631	94,9	605	95,9	32,782	29,648
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	30,417	29,716	617	92,8	587	95,1	28,620	29,121
END OF TREATMENT	0 - < 2 cm	655	99,2	578	88,2	28,950	29,109	661	99,4	598	90,5	25,641	27,358
FU MONTH 18	0 - < 2 cm	617	93,5	545	88,3	24,709	27,435	624	93,8	561	89,9	25,906	28,492
FU MONTH 24	0 - < 2 cm	607	92,0	533	87,8	22,139	26,129	606	91,1	530	87,5	23,648	27,162
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	22,794	26,989	580	87,2	507	87,4	25,115	27,251
BASELINE	>= 2 - < 5 cm	1009	100,0	977	96,8	25,179	26,919	991	100,0	969	97,8	27,279	29,106
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	755	94,7	27,020	28,155	789	79,6	743	94,2	29,655	28,723
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	30,875	29,181	940	94,9	888	94,5	31,569	29,240
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	28,447	28,087	919	92,7	864	94,0	28,549	28,167
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	26,075	28,275	985	99,4	877	89,0	26,150	29,158

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	25,060	28,426	914	92,2	783	85,7	26,948	28,738
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	23,737	27,841	889	89,7	777	87,4	25,611	28,223
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	24,421	29,118	839	84,7	727	86,7	25,493	28,981
BASELINE	>= 5 cm	139	100,0	137	98,6	25,061	28,520	165	100,0	163	98,8	27,198	25,185
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	28,571	30,811	132	80,0	124	93,9	26,882	27,440
WEEK 13	>= 5 cm	130	93,5	124	95,4	30,376	31,526	152	92,1	140	92,1	28,095	27,491
WEEK 25	>= 5 cm	124	89,2	119	96,0	28,011	26,391	150	90,9	147	98,0	26,531	28,917
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	27,200	30,640	163	98,8	151	92,6	26,049	30,281
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	21,807	25,535	148	89,7	129	87,2	26,615	28,680
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	20,721	26,611	141	85,5	117	83,0	21,937	27,390
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	24,092	27,936	135	81,8	116	85,9	23,276	28,563
BASELINE	Missing	3	100,0	2	66,7	16,667	23,570	2	100,0	2	100,0	33,333	0,000
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	44,444	38,490	2	100,0	2	100,0	33,333	0,000
WEEK 13	Missing	3	100,0	3	100,0	55,556	50,918	2	100,0	2	100,0	33,333	0,000
WEEK 25	Missing	3	100,0	3	100,0	44,444	50,918	2	100,0	2	100,0	50,000	23,570
END OF TREATMENT	Missing	3	100,0	3	100,0	55,556	50,918	2	100,0	2	100,0	50,000	23,570
FU MONTH 18	Missing	3	100,0	3	100,0	55,556	50,918	2	100,0	2	100,0	33,333	47,140
FU MONTH 24	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	66,667	47,140
FU MONTH 36	Missing	3	100,0	3	100,0	44,444	38,490	2	100,0	2	100,0	16,667	23,570
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1320	98,0	25,354	27,232	1350	100,0	1310	97,0	26,768	27,963
END OF ANTHRACYCLINE	Yes	1103	81,9	1045	94,7	27,911	28,070	1104	81,8	1042	94,4	30,262	29,096
WEEK 13	Yes	1308	97,1	1244	95,1	31,511	29,298	1324	98,1	1247	94,2	32,291	29,709
WEEK 25	Yes	1277	94,8	1227	96,1	30,019	29,340	1302	96,4	1227	94,2	28,960	28,873

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1213	90,1	27,782	29,205	1350	100,0	1235	91,5	27,179	29,399
FU MONTH 18	Yes	1291	95,8	1145	88,7	25,793	28,570	1298	96,1	1133	87,3	27,626	28,659
FU MONTH 24	Yes	1266	94,0	1109	87,6	23,986	27,639	1260	93,3	1091	86,6	25,634	28,194
FU MONTH 36	Yes	1219	90,5	1062	87,1	24,419	28,618	1195	88,5	1036	86,7	26,544	28,975
BASELINE	No	464	100,0	441	95,0	23,734	26,325	473	100,0	464	98,1	27,802	29,483
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	26,087	27,907	342	72,3	319	93,3	30,721	29,617
WEEK 13	No	380	81,9	362	95,3	30,755	28,061	401	84,8	388	96,8	29,897	27,629
WEEK 25	No	368	79,3	358	97,3	26,257	25,800	386	81,6	373	96,6	26,631	27,539
END OF TREATMENT	No	447	96,3	361	80,8	25,577	27,580	461	97,5	393	85,2	22,222	25,607
FU MONTH 18	No	372	80,2	340	91,4	21,275	25,378	390	82,5	342	87,7	22,904	28,284
FU MONTH 24	No	367	79,1	323	88,0	19,298	24,973	378	79,9	335	88,6	21,393	26,369
FU MONTH 36	No	352	75,9	330	93,8	21,919	27,028	361	76,3	316	87,5	20,570	25,384
Race													
BASELINE	White	1252	100,0	1206	96,3	27,474	27,677	1255	100,0	1213	96,7	29,514	29,059
END OF ANTHRACYCLINE	White	1010	80,7	931	92,2	28,750	29,010	1018	81,1	940	92,3	32,057	30,079
WEEK 13	White	1158	92,5	1086	93,8	33,487	29,728	1183	94,3	1095	92,6	34,429	30,045
WEEK 25	White	1120	89,5	1063	94,9	31,860	30,012	1150	91,6	1070	93,0	31,713	29,609
END OF TREATMENT	White	1238	98,9	1049	84,7	30,251	29,843	1244	99,1	1088	87,5	28,615	30,029
FU MONTH 18	White	1138	90,9	981	86,2	27,727	29,378	1152	91,8	967	83,9	29,886	29,560
FU MONTH 24	White	1115	89,1	942	84,5	26,185	28,681	1120	89,2	941	84,0	28,126	29,174
FU MONTH 36	White	1071	85,5	923	86,2	26,291	29,616	1064	84,8	899	84,5	28,402	29,584
BASELINE	Black	25	100,0	24	96,0	25,000	28,233	31	100,0	30	96,8	46,667	39,731
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	11,111	16,667	15	48,4	15	100,0	42,222	32,038
WEEK 13	Black	21	84,0	17	81,0	35,294	36,268	29	93,5	28	96,6	33,333	38,490

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	40,351	36,139	29	93,5	28	96,6	29,762	33,134
END OF TREATMENT	Black	24	96,0	22	91,7	30,303	33,976	31	100,0	28	90,3	33,333	31,427
FU MONTH 18	Black	23	92,0	17	73,9	25,490	25,082	29	93,5	24	82,8	43,056	41,095
FU MONTH 24	Black	22	88,0	18	81,8	16,667	26,197	28	90,3	23	82,1	26,087	34,752
FU MONTH 36	Black	22	88,0	18	81,8	25,926	31,427	26	83,9	20	76,9	26,667	36,834
BASELINE	Asian	477	100,0	474	99,4	18,847	24,641	484	100,0	480	99,2	19,722	24,272
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	24,561	25,215	375	77,5	368	98,1	25,634	26,237
WEEK 13	Asian	455	95,4	450	98,9	26,667	26,134	466	96,3	465	99,8	25,735	25,794
WEEK 25	Asian	450	94,3	449	99,8	22,866	23,397	465	96,1	459	98,7	21,278	24,328
END OF TREATMENT	Asian	475	99,6	452	95,2	20,428	24,379	484	100,0	464	95,9	19,684	24,009
FU MONTH 18	Asian	447	93,7	434	97,1	18,280	22,738	461	95,2	444	96,3	18,468	23,367
FU MONTH 24	Asian	442	92,7	423	95,7	16,548	22,233	445	91,9	421	94,6	17,023	22,373
FU MONTH 36	Asian	424	88,9	402	94,8	19,071	24,146	425	87,8	398	93,6	18,425	23,564
BASELINE	Other	52	100,0	52	100,0	21,795	22,756	51	100,0	50	98,0	25,333	24,799
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	28,947	30,186	36	70,6	36	100,0	30,556	29,141
WEEK 13	Other	49	94,2	48	98,0	22,917	26,770	45	88,2	45	100,0	27,407	27,788
WEEK 25	Other	49	94,2	49	100,0	23,810	28,054	42	82,4	41	97,6	22,764	27,324
END OF TREATMENT	Other	52	100,0	47	90,4	24,823	31,445	50	98,0	47	94,0	21,986	24,353
FU MONTH 18	Other	50	96,2	48	96,0	20,139	28,961	44	86,3	38	86,4	25,439	31,417
FU MONTH 24	Other	49	94,2	45	91,8	17,778	25,226	43	84,3	39	90,7	22,222	27,924
FU MONTH 36	Other	49	94,2	44	89,8	15,909	26,402	39	76,5	33	84,6	16,162	22,238
BASELINE	Missing	5	100,0	5	100,0	26,667	27,889	2	100,0	1	50,0	33,333	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	26,667	14,907	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	5	100,0	5	100,0	53,333	50,553	2	100,0	2	100,0	16,667	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	33,333	33,333	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	33,333	47,140	2	100,0	1	50,0	66,667	NE
FU MONTH 18	Missing	5	100,0	5	100,0	46,667	44,721	2	100,0	2	100,0	16,667	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	16,667	19,245	2	100,0	2	100,0	16,667	23,570
FU MONTH 36	Missing	5	100,0	5	100,0	13,333	29,814	2	100,0	2	100,0	33,333	47,140

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC05_SG.xls
11AUG2020 16:13

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Appetite Loss Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1763	97,3	8,546	18,318	1823	100,0	1776	97,4	8,859	18,564
END OF ANTHRACYCLINE	n/a	1432	79,1	1345	93,9	19,356	25,418	1446	79,3	1362	94,2	19,824	25,656
WEEK 13	n/a	1688	93,2	1607	95,2	22,236	27,673	1725	94,6	1637	94,9	16,819	24,795
WEEK 25	n/a	1645	90,8	1585	96,4	13,607	22,487	1688	92,6	1602	94,9	9,155	18,538
END OF TREATMENT	n/a	1794	99,1	1572	87,6	9,542	19,564	1811	99,3	1629	90,0	7,080	17,535
FU MONTH 18	n/a	1663	91,8	1486	89,4	5,137	14,363	1688	92,6	1477	87,5	6,116	17,030
FU MONTH 24	n/a	1633	90,2	1432	87,7	5,028	14,570	1638	89,9	1425	87,0	6,175	16,024
FU MONTH 36	n/a	1571	86,7	1390	88,5	5,348	14,675	1556	85,4	1353	87,0	6,233	16,806
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	5,442	14,186	43	100,0	40	93,0	4,167	11,164
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	23,656	24,636	26	60,5	25	96,2	12,000	18,954
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	22,727	26,679	40	93,0	39	97,5	13,675	21,245
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	8,527	14,716	38	88,4	35	92,1	8,571	14,781
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	7,576	15,854	42	97,7	37	88,1	0,901	5,480
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	3,876	10,812	39	90,7	36	92,3	3,704	13,280

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	4,651	11,687	39	90,7	34	87,2	2,941	9,597
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	3,704	10,594	39	90,7	37	94,9	1,802	7,641
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	5,952	15,312	278	100,0	270	97,1	10,000	19,986
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	18,250	25,765	203	73,0	191	94,1	22,339	27,383
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	22,128	27,773	263	94,6	253	96,2	21,080	26,628
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	12,745	20,104	256	92,1	247	96,5	8,502	18,641
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	7,636	16,003	276	99,3	255	92,4	7,712	18,395
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	4,091	12,273	259	93,2	232	89,6	9,195	21,076
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	4,147	14,014	256	92,1	229	89,5	7,715	18,302
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	214	90,3	3,583	11,764	251	90,3	227	90,4	6,021	15,927
BASELINE	1-3 positive nodes	907	100,0	886	97,7	9,631	19,473	900	100,0	878	97,6	8,884	18,207
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	663	93,0	18,854	25,151	707	78,6	668	94,5	19,611	25,219
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	22,484	28,183	854	94,9	804	94,1	15,672	23,943
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	14,147	23,668	836	92,9	789	94,4	8,576	17,075
END OF TREATMENT	1-3 positive nodes	899	99,1	781	86,9	9,603	19,906	897	99,7	814	90,7	6,798	17,267
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	5,510	15,130	852	94,7	746	87,6	5,407	15,514

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	5,082	15,044	830	92,2	726	87,5	5,601	15,137
FU MONTH 36	1-3 positive nodes	804	88,6	704	87,6	5,492	15,443	794	88,2	668	84,1	5,589	16,183
BASELINE	>= 4 positive nodes	596	100,0	576	96,6	8,275	17,883	602	100,0	588	97,7	8,617	18,799
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	20,198	25,733	510	84,7	478	93,7	19,526	25,810
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	21,861	26,983	568	94,4	541	95,2	16,759	25,225
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	13,604	22,201	558	92,7	531	95,2	10,358	20,667
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	10,449	20,687	596	99,0	523	87,8	7,648	18,015
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	5,155	14,326	538	89,4	463	86,1	5,904	17,233
FU MONTH 24	>= 4 positive nodes	516	86,6	452	87,6	5,383	14,318	513	85,2	436	85,0	6,575	16,535
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	6,167	15,010	472	78,4	421	89,2	7,759	18,629
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1403	97,5	8,268	17,708	1448	100,0	1411	97,4	8,575	18,655
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1343	94,0	19,360	25,429	1444	99,7	1361	94,3	19,814	25,663
WEEK 13	Anthracycline containing regimen	1347	93,6	1293	96,0	20,315	26,713	1374	94,9	1303	94,8	14,965	23,775
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	13,423	22,415	1346	93,0	1277	94,9	8,823	18,155
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	9,209	19,171	1444	99,7	1305	90,4	7,024	17,781

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1185	89,2	5,204	14,307	1340	92,5	1181	88,1	5,927	16,937
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	5,265	15,082	1308	90,3	1136	86,9	6,103	16,074
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1110	88,2	5,315	14,532	1244	85,9	1087	87,4	6,378	17,052
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	9,630	20,513	375	100,0	365	97,3	9,954	18,195
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	33,333	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	30,149	30,095	351	93,6	334	95,2	24,052	27,284
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	14,315	22,787	342	91,2	325	95,0	10,462	19,944
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	10,865	21,034	367	97,9	324	88,3	7,305	16,531
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	4,873	14,602	348	92,8	296	85,1	6,869	17,405
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	4,079	12,286	330	88,0	289	87,6	6,459	15,854
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	280	89,7	5,476	15,256	312	83,2	266	85,3	5,639	15,780
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	7,918	17,825	858	100,0	839	97,8	8,621	18,740
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	638	94,9	19,175	25,538	661	77,0	620	93,8	20,860	26,089
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	22,079	27,657	804	93,7	773	96,1	17,076	24,444
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	13,677	21,617	786	91,6	750	95,4	8,889	19,129
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	8,956	18,230	854	99,5	765	89,6	7,582	18,146
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	719	89,8	4,358	13,148	781	91,0	696	89,1	6,897	17,801
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	4,707	14,222	763	88,9	675	88,5	6,519	16,452
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	4,628	12,753	735	85,7	655	89,1	5,751	16,358
BASELINE	Positive (ER and/or PgR positive)	947	100,0	921	97,3	9,121	18,749	965	100,0	937	97,1	9,072	18,413
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	707	93,0	19,519	25,327	785	81,3	742	94,5	18,958	25,274
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	22,383	27,704	921	95,4	864	93,8	16,590	25,117
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	13,539	23,303	902	93,5	852	94,5	9,390	18,009
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	809	86,2	10,095	20,740	957	99,2	864	90,3	6,636	16,973
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	5,867	15,388	907	94,0	781	86,1	5,420	16,293
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	5,330	14,894	875	90,7	750	85,7	5,867	15,634

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	713	87,2	6,031	16,272	821	85,1	698	85,0	6,686	17,216
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	9,524	19,781	260	100,0	254	97,7	11,811	20,330
END OF ANTHRACYCLINE	USA/Canada	109	41,1	101	92,7	16,502	21,408	111	42,7	105	94,6	22,540	27,149
WEEK 13	USA/Canada	242	91,3	229	94,6	24,745	28,253	236	90,8	224	94,9	17,560	24,840
WEEK 25	USA/Canada	234	88,3	225	96,2	13,037	22,225	230	88,5	219	95,2	8,524	17,146
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	8,449	18,573	255	98,1	229	89,8	8,006	18,442
FU MONTH 18	USA/Canada	238	89,8	194	81,5	4,467	12,813	231	88,8	181	78,4	6,998	17,572
FU MONTH 24	USA/Canada	231	87,2	188	81,4	5,496	16,149	224	86,2	176	78,6	4,924	14,289
FU MONTH 36	USA/Canada	223	84,2	180	80,7	5,741	16,463	205	78,8	156	76,1	4,487	14,211
BASELINE	Western Europe	827	100,0	790	95,5	8,397	18,721	822	100,0	786	95,6	8,439	19,058
END OF ANTHRACYCLINE	Western Europe	732	88,5	668	91,3	17,964	26,197	728	88,6	663	91,1	15,837	24,627
WEEK 13	Western Europe	764	92,4	700	91,6	19,667	28,229	778	94,6	709	91,1	14,057	24,578
WEEK 25	Western Europe	738	89,2	693	93,9	12,506	22,825	750	91,2	681	90,8	7,636	17,352
END OF TREATMENT	Western Europe	821	99,3	691	84,2	10,854	21,970	817	99,4	704	86,2	6,581	18,199
FU MONTH 18	Western Europe	754	91,2	650	86,2	6,000	16,339	764	92,9	631	82,6	5,652	17,359
FU MONTH 24	Western Europe	739	89,4	613	82,9	5,057	15,649	747	90,9	620	83,0	5,591	16,108
FU MONTH 36	Western Europe	713	86,2	611	85,7	5,619	15,834	712	86,6	598	84,0	6,132	17,880
BASELINE	Asia Pacific	490	100,0	487	99,4	8,898	17,846	512	100,0	508	99,2	8,071	16,566
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	23,262	24,823	397	77,5	390	98,2	24,957	24,687
WEEK 13	Asia Pacific	466	95,1	465	99,8	25,878	27,014	493	96,3	491	99,6	20,502	24,199
WEEK 25	Asia Pacific	461	94,1	461	100,0	14,895	21,307	492	96,1	488	99,2	10,451	19,168

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	8,621	17,038	512	100,0	491	95,9	6,993	15,013
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	4,425	12,560	485	94,7	473	97,5	6,131	15,266
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	4,837	12,584	470	91,8	448	95,3	6,473	15,616
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	5,502	13,222	453	88,5	432	95,4	6,404	16,140
BASELINE	Latin America	43	100,0	43	100,0	5,426	12,451	47	100,0	46	97,9	9,420	19,453
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	24,138	25,034	32	68,1	32	100,0	21,875	23,355
WEEK 13	Latin America	40	93,0	40	100,0	25,000	24,749	44	93,6	44	100,0	25,000	28,868
WEEK 25	Latin America	39	90,7	39	100,0	11,966	20,925	44	93,6	44	100,0	11,364	20,261
END OF TREATMENT	Latin America	42	97,7	38	90,5	11,404	17,802	45	95,7	42	93,3	11,905	25,313
FU MONTH 18	Latin America	41	95,3	37	90,2	5,405	12,456	42	89,4	40	95,2	10,000	24,108
FU MONTH 24	Latin America	40	93,0	36	90,0	1,852	7,744	41	87,2	39	95,1	8,547	16,610
FU MONTH 36	Latin America	38	88,4	34	89,5	3,922	10,901	37	78,7	36	97,3	5,556	12,599
BASELINE	Other	186	100,0	184	98,9	7,609	16,787	182	100,0	182	100,0	8,608	18,683
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	17,148	25,060	178	97,8	172	96,6	21,512	28,768
WEEK 13	Other	176	94,6	173	98,3	18,882	25,730	174	95,6	169	97,1	14,596	24,613
WEEK 25	Other	173	93,0	167	96,5	15,768	24,765	172	94,5	170	98,8	11,765	21,881
END OF TREATMENT	Other	185	99,5	162	87,6	7,613	16,729	182	100,0	163	89,6	6,953	17,937
FU MONTH 18	Other	171	91,9	153	89,5	4,357	12,503	166	91,2	152	91,6	5,921	18,035
FU MONTH 24	Other	169	90,9	154	91,1	5,628	14,664	156	85,7	142	91,0	8,685	18,485
FU MONTH 36	Other	160	86,0	147	91,9	3,628	11,788	149	81,9	131	87,9	8,397	17,708
Protocol version													
BASELINE	Protocol A	1240	100,0	1208	97,4	8,306	18,703	1246	100,0	1210	97,1	9,091	18,932

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	917	93,2	18,321	24,750	988	79,3	928	93,9	20,115	26,048
WEEK 13	Protocol A	1155	93,1	1108	95,9	20,939	26,898	1180	94,7	1112	94,2	17,026	24,778
WEEK 25	Protocol A	1125	90,7	1087	96,6	12,420	21,123	1157	92,9	1093	94,5	8,966	17,844
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	8,636	18,097	1236	99,2	1117	90,4	7,162	17,806
FU MONTH 18	Protocol A	1142	92,1	1026	89,8	5,133	14,339	1156	92,8	1006	87,0	6,362	17,637
FU MONTH 24	Protocol A	1124	90,6	994	88,4	4,963	14,958	1127	90,4	980	87,0	6,463	16,749
FU MONTH 36	Protocol A	1087	87,7	978	90,0	5,215	14,741	1069	85,8	936	87,6	6,125	17,111
BASELINE	Protocol Amendment B	571	100,0	555	97,2	9,069	17,455	577	100,0	566	98,1	8,363	17,759
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	21,573	26,688	458	79,4	434	94,8	19,201	24,816
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	25,117	29,144	545	94,5	525	96,3	16,381	24,849
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	16,198	25,037	531	92,0	509	95,9	9,561	19,958
END OF TREATMENT	Protocol Amendment B	565	98,9	499	88,3	11,490	22,291	575	99,7	512	89,0	6,901	16,945
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	5,145	14,432	532	92,2	471	88,5	5,591	15,661
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	5,175	13,665	511	88,6	445	87,1	5,543	14,298
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	5,663	14,531	487	84,4	417	85,6	6,475	16,118
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	5,869	15,113	321	100,0	310	96,6	9,247	19,165
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	19,048	25,616	229	71,3	216	94,3	21,142	26,716
WEEK 13	0 positive nodes	294	95,5	279	94,9	22,222	27,557	303	94,4	292	96,4	20,091	26,064
WEEK 25	0 positive nodes	287	93,2	281	97,9	12,100	19,414	294	91,6	282	95,9	8,511	18,183
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	7,626	15,949	318	99,1	292	91,8	6,849	17,441
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	4,056	12,027	298	92,8	268	89,9	8,458	20,271

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	4,233	13,625	295	91,9	263	89,2	7,098	17,483
FU MONTH 36	0 positive nodes	283	91,9	259	91,5	3,604	11,549	290	90,3	264	91,0	5,429	15,104
BASELINE	>= 1 positive nodes	1503	100,0	1462	97,3	9,097	18,868	1502	100,0	1466	97,6	8,777	18,441
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	19,413	25,392	1217	81,0	1146	94,2	19,575	25,456
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	22,239	27,708	1422	94,7	1345	94,6	16,109	24,463
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	13,931	23,090	1394	92,8	1320	94,7	9,293	18,616
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1301	87,4	9,941	20,219	1493	99,4	1337	89,6	7,130	17,561
FU MONTH 18	>= 1 positive nodes	1371	91,2	1223	89,2	5,369	14,811	1390	92,5	1209	87,0	5,597	16,188
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	5,198	14,764	1343	89,4	1162	86,5	5,967	15,676
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	5,747	15,278	1266	84,3	1089	86,0	6,428	17,195
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	854	97,8	8,821	18,339	885	100,0	868	98,1	8,295	17,692
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	16,765	22,987	726	82,0	693	95,5	18,038	24,112
WEEK 13	Premenopausal	841	96,3	806	95,8	17,411	25,008	852	96,3	809	95,0	13,844	22,570
WEEK 25	Premenopausal	825	94,5	800	97,0	10,667	20,223	838	94,7	799	95,3	7,968	16,576
END OF TREATMENT	Premenopausal	866	99,2	765	88,3	7,538	16,878	881	99,5	813	92,3	5,986	15,858
FU MONTH 18	Premenopausal	819	93,8	724	88,4	3,959	12,629	835	94,4	740	88,6	4,955	15,298
FU MONTH 24	Premenopausal	803	92,0	705	87,8	4,444	13,846	807	91,2	707	87,6	4,903	13,436

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	4,663	13,791	773	87,3	669	86,5	5,282	15,217
BASELINE	Postmenopausal	933	100,0	904	96,9	8,296	18,328	929	100,0	900	96,9	9,333	19,302
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	664	92,4	22,088	27,475	711	76,5	662	93,1	21,803	27,127
WEEK 13	Postmenopausal	842	90,2	797	94,7	27,143	29,383	864	93,0	820	94,9	19,837	26,550
WEEK 25	Postmenopausal	815	87,4	780	95,7	16,667	24,271	841	90,5	796	94,6	10,427	20,309
END OF TREATMENT	Postmenopausal	923	98,9	803	87,0	11,457	21,676	921	99,1	808	87,7	8,210	19,065
FU MONTH 18	Postmenopausal	839	89,9	759	90,5	6,280	15,789	844	90,9	729	86,4	7,270	18,586
FU MONTH 24	Postmenopausal	825	88,4	723	87,6	5,625	15,265	823	88,6	713	86,6	7,433	18,169
FU MONTH 36	Postmenopausal	801	85,9	714	89,1	6,022	15,476	776	83,5	678	87,4	7,178	18,233
BASELINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	8	88,9	16,667	25,198
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	9,524	16,265
WEEK 13	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	9	100,0	8	88,9	8,333	15,430
WEEK 25	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	0,000	0,000
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	9	100,0	8	88,9	4,167	11,785
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	9	100,0	8	88,9	8,333	15,430
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	8	88,9	5	62,5	6,667	14,907
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	7	77,8	6	85,7	5,556	13,608
Age II													
BASELINE	< 65	1581	100,0	1543	97,6	8,728	18,524	1604	100,0	1568	97,8	8,695	18,455
END OF ANTHRACYCLINE	< 65	1268	80,2	1198	94,5	18,559	24,857	1287	80,2	1220	94,8	19,645	25,318
WEEK 13	< 65	1497	94,7	1428	95,4	20,775	26,929	1529	95,3	1455	95,2	16,014	24,213

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	12,912	21,701	1501	93,6	1429	95,2	8,654	17,657
END OF TREATMENT	< 65	1569	99,2	1384	88,2	8,646	18,058	1596	99,5	1446	90,6	6,939	17,191
FU MONTH 18	< 65	1474	93,2	1314	89,1	4,820	14,088	1497	93,3	1320	88,2	6,111	16,865
FU MONTH 24	< 65	1446	91,5	1263	87,3	4,671	14,112	1450	90,4	1269	87,5	6,015	15,766
FU MONTH 36	< 65	1390	87,9	1232	88,6	4,951	14,086	1383	86,2	1206	87,2	6,136	16,663
BASELINE	>= 65	230	100,0	220	95,7	7,273	16,785	219	100,0	208	95,0	10,096	19,373
END OF ANTHRACYCLINE	>= 65	164	71,3	147	89,6	25,850	28,880	159	72,6	142	89,3	21,362	28,446
WEEK 13	>= 65	191	83,0	179	93,7	33,892	30,696	196	89,5	182	92,9	23,260	28,291
WEEK 25	>= 65	181	78,7	178	98,3	19,101	27,395	187	85,4	173	92,5	13,295	24,310
END OF TREATMENT	>= 65	225	97,8	188	83,6	16,135	27,465	215	98,2	183	85,1	8,197	20,063
FU MONTH 18	>= 65	189	82,2	172	91,0	7,558	16,153	191	87,2	157	82,2	6,157	18,421
FU MONTH 24	>= 65	187	81,3	169	90,4	7,692	17,442	188	85,8	156	83,0	7,479	17,990
FU MONTH 36	>= 65	181	78,7	158	87,3	8,439	18,407	173	79,0	147	85,0	7,029	17,977
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	13,978	26,908	24	100,0	24	100,0	6,944	13,828
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	19,608	26,507	17	70,8	16	94,1	20,833	20,638
WEEK 13	Grade 1	31	96,9	30	96,8	24,444	32,676	23	95,8	22	95,7	25,758	22,845
WEEK 25	Grade 1	31	96,9	29	93,5	18,391	28,986	23	95,8	22	95,7	13,636	19,678
END OF TREATMENT	Grade 1	31	96,9	27	87,1	4,938	12,067	24	100,0	22	91,7	9,091	18,349
FU MONTH 18	Grade 1	30	93,8	27	90,0	2,469	8,896	23	95,8	22	95,7	3,030	9,808
FU MONTH 24	Grade 1	28	87,5	27	96,4	6,173	16,111	23	95,8	21	91,3	4,762	15,936
FU MONTH 36	Grade 1	27	84,4	26	96,3	3,846	10,860	22	91,7	20	90,9	6,667	13,680
BASELINE	Grade 2	552	100,0	537	97,3	7,325	16,166	557	100,0	543	97,5	8,594	17,992
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	19,340	24,860	446	80,1	424	95,1	20,283	26,582

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	21,948	28,126	524	94,1	503	96,0	17,893	25,119
WEEK 25	Grade 2	494	89,5	479	97,0	13,292	21,927	515	92,5	493	95,7	8,452	17,089
END OF TREATMENT	Grade 2	548	99,3	484	88,3	9,917	20,188	553	99,3	496	89,7	7,191	17,208
FU MONTH 18	Grade 2	507	91,8	457	90,1	5,398	15,296	517	92,8	448	86,7	5,655	15,853
FU MONTH 24	Grade 2	501	90,8	448	89,4	4,613	13,692	500	89,8	431	86,2	6,806	17,611
FU MONTH 36	Grade 2	487	88,2	438	89,9	5,023	14,267	476	85,5	413	86,8	5,892	17,074
BASELINE	Grade 3	1161	100,0	1132	97,5	8,981	18,880	1173	100,0	1141	97,3	9,056	18,984
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	19,315	25,608	919	78,3	860	93,6	19,380	25,363
WEEK 13	Grade 3	1088	93,7	1030	94,7	22,265	27,344	1114	95,0	1052	94,4	16,065	24,776
WEEK 25	Grade 3	1059	91,2	1019	96,2	13,477	22,295	1087	92,7	1025	94,3	9,431	19,319
END OF TREATMENT	Grade 3	1150	99,1	1000	87,0	9,667	19,557	1165	99,3	1051	90,2	6,977	17,816
FU MONTH 18	Grade 3	1067	91,9	948	88,8	5,063	14,045	1085	92,5	948	87,4	6,118	17,265
FU MONTH 24	Grade 3	1046	90,1	903	86,3	5,168	14,820	1053	89,8	917	87,1	5,889	15,316
FU MONTH 36	Grade 3	1002	86,3	874	87,2	5,683	15,203	999	85,2	868	86,9	6,336	16,777
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	8,466	19,827	69	100,0	68	98,6	8,333	17,634
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	20,139	27,280	64	92,8	62	96,9	22,581	24,720
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	22,951	27,582	64	92,8	60	93,8	17,778	22,522
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	16,092	26,668	63	91,3	62	98,4	8,602	15,895
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	6,557	17,018	69	100,0	60	87,0	7,222	15,147
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	5,556	14,112	63	91,3	59	93,7	10,734	22,693

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	5,556	16,823	62	89,9	56	90,3	6,548	14,798
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	3,205	9,923	59	85,5	52	88,1	7,051	16,616
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	7,885	18,171	715	100,0	687	96,1	7,860	17,899
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	546	92,2	19,231	27,064	572	80,0	522	91,3	18,966	25,878
WEEK 13	Breast conserving surgery	677	93,0	638	94,2	22,518	29,468	673	94,1	633	94,1	16,693	25,306
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	14,867	24,258	654	91,5	613	93,7	8,428	18,268
END OF TREATMENT	Breast conserving surgery	722	99,2	623	86,3	10,380	20,688	711	99,4	621	87,3	6,388	17,465
FU MONTH 18	Breast conserving surgery	678	93,1	596	87,9	5,649	14,583	659	92,2	561	85,1	5,882	17,109
FU MONTH 24	Breast conserving surgery	666	91,5	575	86,3	5,739	16,577	644	90,1	555	86,2	6,066	16,309
FU MONTH 36	Breast conserving surgery	651	89,4	561	86,2	5,169	15,007	616	86,2	536	87,0	5,846	16,401
BASELINE	Mastectomy	1083	100,0	1057	97,6	8,988	18,411	1107	100,0	1088	98,3	9,467	18,948
END OF ANTHRACYCLINE	Mastectomy	840	77,6	799	95,1	19,441	24,246	873	78,9	839	96,1	20,342	25,529
WEEK 13	Mastectomy	1011	93,4	969	95,8	22,050	26,439	1051	94,9	1003	95,4	16,916	24,486
WEEK 25	Mastectomy	980	90,5	946	96,5	12,755	21,179	1033	93,3	988	95,6	9,615	18,705
END OF TREATMENT	Mastectomy	1072	99,0	949	88,5	8,992	18,781	1099	99,3	1007	91,6	7,481	17,563
FU MONTH 18	Mastectomy	985	91,0	890	90,4	4,794	14,211	1028	92,9	915	89,0	6,266	16,998
FU MONTH 24	Mastectomy	967	89,3	857	88,6	4,551	13,041	993	89,7	869	87,5	6,252	15,857

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	5,468	14,454	939	84,8	817	87,0	6,487	17,073
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	7,494	16,944	665	100,0	641	96,4	8,008	17,027
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	482	92,9	16,805	24,718	523	78,6	493	94,3	19,608	25,916
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	21,498	26,988	631	94,9	605	95,9	16,253	23,848
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	13,951	23,033	617	92,8	588	95,3	7,766	16,911
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	8,854	18,565	661	99,4	599	90,6	6,900	16,824
FU MONTH 18	0 - < 2 cm	617	93,5	546	88,5	4,579	12,505	624	93,8	561	89,9	5,823	16,480
FU MONTH 24	0 - < 2 cm	607	92,0	533	87,8	4,878	14,920	606	91,1	530	87,5	6,478	16,072
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	4,317	12,794	580	87,2	507	87,4	6,706	16,862
BASELINE	>= 2 - < 5 cm	1009	100,0	979	97,0	9,159	18,860	991	100,0	971	98,0	9,681	19,911
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	755	94,7	21,148	26,011	789	79,6	743	94,2	20,682	25,813
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	22,656	28,079	940	94,9	890	94,7	17,903	25,574
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	13,485	22,429	919	92,7	865	94,1	10,058	19,453
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	9,869	20,089	985	99,4	876	88,9	6,659	17,313

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	5,341	15,258	914	92,2	785	85,9	6,667	17,802
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	5,096	14,564	889	89,7	776	87,3	6,143	16,446
FU MONTH 36	>= 2 - < 5 cm	857	84,9	761	88,8	5,650	15,443	839	84,7	728	86,8	5,815	16,625
BASELINE	>= 5 cm	139	100,0	137	98,6	9,246	20,504	165	100,0	162	98,2	7,202	15,639
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	18,095	23,583	132	80,0	124	93,9	15,591	23,449
WEEK 13	>= 5 cm	130	93,5	125	96,2	22,133	27,417	152	92,1	140	92,1	12,619	23,474
WEEK 25	>= 5 cm	124	89,2	119	96,0	12,605	20,351	150	90,9	147	98,0	9,524	19,113
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	10,400	20,485	163	98,8	152	93,3	10,307	21,094
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	6,231	15,947	148	89,7	129	87,2	4,134	14,438
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	5,405	13,135	141	85,5	117	83,0	5,128	12,847
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	8,251	17,260	135	81,8	116	85,9	6,897	17,865
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	16,667	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	3	100,0	3	100,0	44,444	50,918	2	100,0	2	100,0	0,000	0,000
WEEK 25	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
FU MONTH 18	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1320	98,0	8,106	18,147	1350	100,0	1312	97,2	8,537	18,180
END OF ANTHRACYCLINE	Yes	1103	81,9	1046	94,8	18,961	25,311	1104	81,8	1043	94,5	18,408	24,995
WEEK 13	Yes	1308	97,1	1246	95,3	21,589	27,774	1324	98,1	1250	94,4	16,133	24,635
WEEK 25	Yes	1277	94,8	1227	96,1	13,665	22,665	1302	96,4	1229	94,4	9,113	18,643

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1212	90,0	9,626	19,792	1350	100,0	1236	91,6	7,012	17,420
FU MONTH 18	Yes	1291	95,8	1146	88,8	5,381	14,781	1298	96,1	1133	87,3	5,649	16,443
FU MONTH 24	Yes	1266	94,0	1109	87,6	5,200	15,055	1260	93,3	1091	86,6	6,049	15,838
FU MONTH 36	Yes	1219	90,5	1060	87,0	5,597	15,266	1195	88,5	1037	86,8	6,107	16,608
BASELINE	No	464	100,0	443	95,5	9,857	18,777	473	100,0	464	98,1	9,770	19,604
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	20,736	25,783	342	72,3	319	93,3	24,451	27,239
WEEK 13	No	380	81,9	361	95,0	24,469	27,243	401	84,8	387	96,5	19,035	25,210
WEEK 25	No	368	79,3	358	97,3	13,408	21,899	386	81,6	373	96,6	9,294	18,208
END OF TREATMENT	No	447	96,3	360	80,5	9,259	18,802	461	97,5	393	85,2	7,294	17,911
FU MONTH 18	No	372	80,2	340	91,4	4,314	12,841	390	82,5	344	88,2	7,655	18,779
FU MONTH 24	No	367	79,1	323	88,0	4,438	12,772	378	79,9	334	88,4	6,587	16,637
FU MONTH 36	No	352	75,9	330	93,8	4,545	12,581	361	76,3	316	87,5	6,646	17,461
Race													
BASELINE	White	1252	100,0	1207	96,4	8,478	18,585	1255	100,0	1215	96,8	8,669	18,645
END OF ANTHRACYCLINE	White	1010	80,7	933	92,4	17,185	25,256	1018	81,1	941	92,4	16,968	25,245
WEEK 13	White	1158	92,5	1086	93,8	19,920	27,401	1183	94,3	1097	92,7	14,403	24,022
WEEK 25	White	1120	89,5	1063	94,9	12,951	22,975	1150	91,6	1072	93,2	8,333	17,788
END OF TREATMENT	White	1238	98,9	1047	84,6	9,806	20,649	1244	99,1	1089	87,5	6,856	18,188
FU MONTH 18	White	1138	90,9	982	86,3	5,363	14,997	1152	91,8	968	84,0	5,613	16,933
FU MONTH 24	White	1115	89,1	942	84,5	5,096	15,444	1120	89,2	941	84,0	5,739	15,983
FU MONTH 36	White	1071	85,5	921	86,0	5,320	15,524	1064	84,8	900	84,6	6,000	17,253
BASELINE	Black	25	100,0	24	96,0	11,111	23,399	31	100,0	30	96,8	18,889	29,921
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	11,111	16,667	15	48,4	15	100,0	44,444	34,885
WEEK 13	Black	21	84,0	17	81,0	29,412	26,040	29	93,5	28	96,6	32,143	33,311

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	12,281	22,800	29	93,5	28	96,6	13,095	24,578
END OF TREATMENT	Black	24	96,0	22	91,7	10,606	18,930	31	100,0	28	90,3	17,857	26,422
FU MONTH 18	Black	23	92,0	17	73,9	5,882	17,620	29	93,5	24	82,8	19,444	30,954
FU MONTH 24	Black	22	88,0	18	81,8	5,556	17,150	28	90,3	22	78,6	12,121	19,370
FU MONTH 36	Black	22	88,0	18	81,8	11,111	19,803	26	83,9	20	76,9	15,000	25,305
BASELINE	Asian	477	100,0	475	99,6	9,053	17,984	484	100,0	480	99,2	8,681	17,261
END OF ANTHRACYCLINE	Asian	370	77,6	360	97,3	24,907	25,127	375	77,5	368	98,1	25,996	25,044
WEEK 13	Asian	455	95,4	450	98,9	27,333	27,805	466	96,3	465	99,8	21,147	24,655
WEEK 25	Asian	450	94,3	449	99,8	15,516	21,462	465	96,1	459	98,7	10,603	19,551
END OF TREATMENT	Asian	475	99,6	452	95,2	8,628	16,516	484	100,0	464	95,9	6,753	14,611
FU MONTH 18	Asian	447	93,7	434	97,1	4,531	12,913	461	95,2	444	96,3	6,156	15,096
FU MONTH 24	Asian	442	92,7	423	95,7	5,043	12,809	445	91,9	421	94,6	6,651	15,873
FU MONTH 36	Asian	424	88,9	402	94,8	5,307	12,656	425	87,8	398	93,6	6,365	15,468
BASELINE	Other	52	100,0	52	100,0	3,846	10,753	51	100,0	50	98,0	9,333	19,095
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	23,684	26,743	36	70,6	36	100,0	21,296	22,752
WEEK 13	Other	49	94,2	49	100,0	25,850	27,441	45	88,2	45	100,0	21,481	29,435
WEEK 25	Other	49	94,2	49	100,0	11,565	21,028	42	82,4	41	97,6	12,195	20,758
END OF TREATMENT	Other	52	100,0	47	90,4	12,057	22,442	50	98,0	47	94,0	9,220	20,503
FU MONTH 18	Other	50	96,2	48	96,0	6,250	13,148	44	86,3	39	88,6	10,256	24,368
FU MONTH 24	Other	49	94,2	45	91,8	3,704	10,594	43	84,3	39	90,7	8,547	16,610
FU MONTH 36	Other	49	94,2	44	89,8	4,545	11,571	39	76,5	33	84,6	6,061	13,056
BASELINE	Missing	5	100,0	5	100,0	13,333	18,257	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	16,667	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	8,333	16,667	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC06_SG.xls
11AUG2020 16:14

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Constipation Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1764	97,4	8,862	19,058	1823	100,0	1775	97,4	9,897	19,394
END OF ANTHRACYCLINE	n/a	1432	79,1	1342	93,7	17,362	25,470	1446	79,3	1362	94,2	18,184	26,307
WEEK 13	n/a	1688	93,2	1600	94,8	9,583	19,041	1725	94,6	1638	95,0	13,777	22,730
WEEK 25	n/a	1645	90,8	1583	96,2	7,749	17,225	1688	92,6	1602	94,9	9,904	20,382
END OF TREATMENT	n/a	1794	99,1	1571	87,6	8,466	17,599	1811	99,3	1628	89,9	10,524	20,102
FU MONTH 18	n/a	1663	91,8	1484	89,2	11,905	21,807	1688	92,6	1475	87,4	11,254	21,371
FU MONTH 24	n/a	1633	90,2	1433	87,8	10,561	20,128	1638	89,9	1426	87,1	10,262	20,555
FU MONTH 36	n/a	1571	86,7	1392	88,6	10,297	20,560	1556	85,4	1348	86,6	10,682	21,057
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	8,844	18,973	43	100,0	40	93,0	11,667	17,783
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	13,978	20,681	26	60,5	25	96,2	18,667	27,352
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	9,848	16,981	40	93,0	39	97,5	13,675	19,821
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	10,853	23,817	38	88,4	35	92,1	9,524	19,083
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	5,303	12,333	42	97,7	37	88,1	10,811	17,663
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	12,403	19,277	39	90,7	36	92,3	14,815	23,155

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	9,302	18,294	39	90,7	34	87,2	8,824	17,034
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	11,111	18,803	39	90,7	37	94,9	9,910	15,446
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	9,259	20,674	278	100,0	271	97,5	9,594	19,410
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	17,228	25,111	203	73,0	191	94,1	18,499	25,035
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	10,496	18,579	263	94,6	253	96,2	14,888	23,806
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	8,439	16,920	256	92,1	246	96,1	8,266	17,284
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	226	89,0	7,670	15,402	276	99,3	255	92,4	10,458	20,159
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	219	89,0	10,198	20,506	259	93,2	232	89,6	9,483	19,521
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	10,686	19,546	256	92,1	230	89,8	9,275	19,227
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	9,457	18,185	251	90,3	227	90,4	12,188	22,465
BASELINE	1-3 positive nodes	907	100,0	886	97,7	8,427	18,862	900	100,0	876	97,3	9,741	18,761
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	662	92,8	17,372	25,380	707	78,6	667	94,3	17,241	25,131
WEEK 13	1-3 positive nodes	847	93,4	802	94,7	9,393	19,364	854	94,9	806	94,4	13,482	22,725
WEEK 25	1-3 positive nodes	825	91,0	786	95,3	7,506	16,789	836	92,9	790	94,5	10,591	20,936
END OF TREATMENT	1-3 positive nodes	899	99,1	781	86,9	9,134	18,233	897	99,7	813	90,6	10,332	19,709
FU MONTH 18	1-3 positive nodes	838	92,4	737	87,9	12,800	22,600	852	94,7	744	87,3	11,156	21,658

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	11,401	21,192	830	92,2	726	87,5	10,331	20,836
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	11,064	21,699	794	88,2	665	83,8	10,326	20,786
BASELINE	>= 4 positive nodes	596	100,0	577	96,8	9,359	18,661	602	100,0	588	97,7	10,147	20,430
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	471	95,0	17,622	26,064	510	84,7	479	93,9	19,346	28,305
WEEK 13	>= 4 positive nodes	547	91,8	519	94,9	9,441	18,947	568	94,4	540	95,1	13,704	22,461
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	7,544	17,395	558	92,7	531	95,2	9,667	20,949
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	8,077	17,888	596	99,0	523	87,8	10,835	20,876
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	11,271	21,349	538	89,4	463	86,1	12,023	21,643
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	9,272	18,746	513	85,2	436	85,0	10,780	21,046
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	9,368	19,929	472	78,4	419	88,8	10,501	21,158
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1404	97,6	8,167	18,057	1448	100,0	1410	97,4	9,669	19,463
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1340	93,8	17,363	25,480	1444	99,7	1361	94,3	18,197	26,312
WEEK 13	Anthracycline containing regimen	1347	93,6	1287	95,5	8,910	18,169	1374	94,9	1303	94,8	12,817	22,140
WEEK 25	Anthracycline containing regimen	1311	91,1	1257	95,9	7,637	17,343	1346	93,0	1277	94,9	9,867	20,743
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	8,546	17,889	1444	99,7	1303	90,2	10,924	20,761

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1184	89,1	11,740	22,314	1340	92,5	1179	88,0	11,252	21,578
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	10,636	20,542	1308	90,3	1137	86,9	10,642	21,005
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	10,651	21,119	1244	85,9	1083	87,1	10,834	21,391
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	11,574	22,364	375	100,0	365	97,3	10,776	19,127
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	0,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	313	91,8	12,354	22,089	351	93,6	335	95,4	17,512	24,575
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	8,180	16,781	342	91,2	325	95,0	10,051	18,926
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	8,148	16,418	367	97,9	325	88,6	8,923	17,144
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	300	89,8	12,556	19,700	348	92,8	296	85,1	11,261	20,559
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	10,256	18,409	330	88,0	289	87,6	8,766	18,635
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	8,897	18,146	312	83,2	265	84,9	10,063	19,661
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	843	97,6	9,411	19,522	858	100,0	839	97,8	10,330	20,058
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	636	94,6	16,824	25,478	661	77,0	621	93,9	17,821	25,205
WEEK 13	Negative (ER and PgR negative)	815	94,3	775	95,1	9,677	18,626	804	93,7	772	96,0	13,644	23,174
WEEK 25	Negative (ER and PgR negative)	799	92,5	773	96,7	7,417	16,612	786	91,6	750	95,4	9,067	19,045
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	8,694	17,461	854	99,5	764	89,5	9,904	19,140
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	717	89,5	11,483	21,429	781	91,0	695	89,0	10,983	21,004
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	10,183	19,829	763	88,9	676	88,6	9,665	19,842
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	10,128	19,739	735	85,7	652	88,7	10,020	19,773
BASELINE	Positive (ER and/or PgR positive)	947	100,0	921	97,3	8,360	18,620	965	100,0	936	97,0	9,509	18,782
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	17,847	25,470	785	81,3	741	94,4	18,489	27,208
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	825	94,5	9,495	19,433	921	95,4	866	94,0	13,895	22,340
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	8,066	17,795	902	93,5	852	94,5	10,642	21,473
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	808	86,1	8,251	17,737	957	99,2	864	90,3	11,073	20,912
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	12,299	22,161	907	94,0	780	86,0	11,496	21,703
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	10,916	20,413	875	90,7	750	85,7	10,800	21,176

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	10,458	21,322	821	85,1	696	84,8	11,303	22,189
Geographical region II													
BASELINE	USA/Canada	265	100,0	260	98,1	9,744	20,690	260	100,0	255	98,1	10,850	19,618
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	20,588	25,711	111	42,7	105	94,6	19,365	27,651
WEEK 13	USA/Canada	242	91,3	229	94,6	8,588	17,907	236	90,8	224	94,9	17,262	25,247
WEEK 25	USA/Canada	234	88,3	225	96,2	6,222	15,132	230	88,5	219	95,2	10,502	19,058
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	6,912	14,640	255	98,1	228	89,4	10,673	19,742
FU MONTH 18	USA/Canada	238	89,8	194	81,5	13,402	23,342	231	88,8	181	78,4	11,786	21,854
FU MONTH 24	USA/Canada	231	87,2	188	81,4	12,411	21,519	224	86,2	177	79,0	10,734	20,512
FU MONTH 36	USA/Canada	223	84,2	180	80,7	5,556	14,740	205	78,8	156	76,1	11,752	21,354
BASELINE	Western Europe	827	100,0	790	95,5	8,354	19,441	822	100,0	784	95,4	8,716	18,888
END OF ANTHRACYCLINE	Western Europe	732	88,5	664	90,7	18,424	26,535	728	88,6	663	91,1	19,105	28,390
WEEK 13	Western Europe	764	92,4	693	90,7	8,658	19,352	778	94,6	710	91,3	12,770	23,346
WEEK 25	Western Europe	738	89,2	692	93,8	7,707	18,067	750	91,2	681	90,8	10,279	22,479
END OF TREATMENT	Western Europe	821	99,3	690	84,0	8,986	18,744	817	99,4	704	86,2	11,080	21,856
FU MONTH 18	Western Europe	754	91,2	648	85,9	12,037	23,129	764	92,9	629	82,3	11,712	22,937
FU MONTH 24	Western Europe	739	89,4	614	83,1	10,803	20,351	747	90,9	620	83,0	10,376	22,134
FU MONTH 36	Western Europe	713	86,2	613	86,0	11,637	22,275	712	86,6	594	83,4	10,606	21,853
BASELINE	Asia Pacific	490	100,0	487	99,4	10,130	18,458	512	100,0	508	99,2	10,499	19,506
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	16,667	24,132	397	77,5	390	98,2	15,897	22,376
WEEK 13	Asia Pacific	466	95,1	465	99,8	11,971	19,391	493	96,3	492	99,8	12,940	19,778
WEEK 25	Asia Pacific	461	94,1	461	100,0	8,966	16,929	492	96,1	488	99,2	8,880	17,180

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	9,698	18,311	512	100,0	491	95,9	9,165	17,424
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	11,799	19,311	485	94,7	473	97,5	10,007	18,752
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	9,751	18,207	470	91,8	448	95,3	9,970	18,516
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	11,483	20,801	453	88,5	431	95,1	10,596	19,652
BASELINE	Latin America	43	100,0	43	100,0	10,853	15,805	47	100,0	46	97,9	11,594	18,879
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	13,793	20,925	32	68,1	32	100,0	18,750	26,690
WEEK 13	Latin America	40	93,0	40	100,0	12,500	16,343	44	93,6	43	97,7	18,605	24,454
WEEK 25	Latin America	39	90,7	39	100,0	9,402	15,196	44	93,6	44	100,0	12,121	19,143
END OF TREATMENT	Latin America	42	97,7	38	90,5	4,386	11,419	45	95,7	42	93,3	9,524	15,241
FU MONTH 18	Latin America	41	95,3	37	90,2	9,910	17,329	42	89,4	40	95,2	14,167	19,810
FU MONTH 24	Latin America	40	93,0	36	90,0	7,407	14,055	41	87,2	39	95,1	8,547	18,286
FU MONTH 36	Latin America	38	88,4	34	89,5	4,902	14,524	37	78,7	36	97,3	10,185	19,222
BASELINE	Other	186	100,0	184	98,9	5,978	16,907	182	100,0	182	100,0	11,538	20,905
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	13,487	24,336	178	97,8	172	96,6	18,992	25,255
WEEK 13	Other	176	94,6	173	98,3	7,514	18,365	174	95,6	169	97,1	14,596	23,793
WEEK 25	Other	173	93,0	166	96,0	6,225	17,448	172	94,5	170	98,8	10,000	22,012
END OF TREATMENT	Other	185	99,5	162	87,6	5,761	14,665	182	100,0	163	89,6	12,270	21,262
FU MONTH 18	Other	171	91,9	153	89,5	10,240	22,058	166	91,2	152	91,6	11,842	22,173
FU MONTH 24	Other	169	90,9	154	91,1	10,390	23,653	156	85,7	142	91,0	10,563	20,386
FU MONTH 36	Other	160	86,0	147	91,9	8,390	18,647	149	81,9	131	87,9	10,178	22,224
Protocol version													
BASELINE	Protocol A	1240	100,0	1208	97,4	9,023	19,721	1246	100,0	1208	97,0	10,017	19,894

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	914	92,9	17,141	25,548	988	79,3	928	93,9	18,499	26,620
WEEK 13	Protocol A	1155	93,1	1103	95,5	9,580	19,155	1180	94,7	1113	94,3	13,866	22,583
WEEK 25	Protocol A	1125	90,7	1085	96,4	7,558	16,643	1157	92,9	1093	94,5	9,668	20,251
END OF TREATMENT	Protocol A	1229	99,1	1072	87,2	8,333	17,375	1236	99,2	1115	90,2	10,463	20,077
FU MONTH 18	Protocol A	1142	92,1	1025	89,8	11,350	21,250	1156	92,8	1005	86,9	11,211	21,310
FU MONTH 24	Protocol A	1124	90,6	995	88,5	10,720	20,035	1127	90,4	981	87,0	10,262	20,510
FU MONTH 36	Protocol A	1087	87,7	980	90,2	10,340	20,484	1069	85,8	931	87,1	10,705	21,166
BASELINE	Protocol Amendment B	571	100,0	556	97,4	8,513	17,544	577	100,0	567	98,3	9,641	18,298
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	17,835	25,325	458	79,4	434	94,8	17,512	25,641
WEEK 13	Protocol Amendment B	533	93,3	497	93,2	9,591	18,805	545	94,5	525	96,3	13,587	23,060
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	8,166	18,441	531	92,0	509	95,9	10,413	20,670
END OF TREATMENT	Protocol Amendment B	565	98,9	499	88,3	8,751	18,086	575	99,7	513	89,2	10,656	20,176
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	13,145	22,977	532	92,2	470	88,3	11,348	21,523
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	10,198	20,358	511	88,6	445	87,1	10,262	20,676
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	10,194	20,763	487	84,4	417	85,6	10,631	20,838
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	9,192	20,377	321	100,0	311	96,9	9,861	19,194
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	16,746	24,487	229	71,3	216	94,3	18,519	25,246
WEEK 13	0 positive nodes	294	95,5	279	94,9	10,394	18,309	303	94,4	292	96,4	14,726	23,286
WEEK 25	0 positive nodes	287	93,2	280	97,6	8,810	18,120	294	91,6	281	95,6	8,422	17,487
END OF TREATMENT	0 positive nodes	305	99,0	270	88,5	7,284	14,950	318	99,1	292	91,8	10,502	19,833
FU MONTH 18	0 positive nodes	292	94,8	262	89,7	10,560	20,290	298	92,8	268	89,9	10,199	20,082

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	10,450	19,310	295	91,9	264	89,5	9,217	18,929
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	9,744	18,267	290	90,3	264	91,0	11,869	21,609
BASELINE	>= 1 positive nodes	1503	100,0	1463	97,3	8,795	18,782	1502	100,0	1464	97,5	9,904	19,443
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1133	93,7	17,476	25,656	1217	81,0	1146	94,2	18,121	26,512
WEEK 13	>= 1 positive nodes	1394	92,7	1321	94,8	9,412	19,194	1422	94,7	1346	94,7	13,571	22,611
WEEK 25	>= 1 positive nodes	1358	90,4	1303	95,9	7,521	17,025	1394	92,8	1321	94,8	10,220	20,938
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1301	87,4	8,711	18,096	1493	99,4	1336	89,5	10,529	20,168
FU MONTH 18	>= 1 positive nodes	1371	91,2	1222	89,1	12,193	22,116	1390	92,5	1207	86,8	11,489	21,647
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	10,584	20,307	1343	89,4	1162	86,5	10,499	20,907
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	10,424	21,056	1266	84,3	1084	85,6	10,394	20,921
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	854	97,8	8,548	18,148	885	100,0	868	98,1	8,909	18,601
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	16,642	25,119	726	82,0	693	95,5	18,663	27,200
WEEK 13	Premenopausal	841	96,3	804	95,6	8,582	18,059	852	96,3	809	95,0	13,391	21,827
WEEK 25	Premenopausal	825	94,5	799	96,8	7,885	17,354	838	94,7	800	95,5	9,792	19,590
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	8,388	18,060	881	99,5	811	92,1	10,399	19,810
FU MONTH 18	Premenopausal	819	93,8	724	88,4	12,293	22,333	835	94,4	739	88,5	11,186	20,560
FU MONTH 24	Premenopausal	803	92,0	705	87,8	10,165	19,358	807	91,2	708	87,7	9,557	19,372

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	10,005	20,629	773	87,3	666	86,2	10,310	21,093
BASELINE	Postmenopausal	933	100,0	905	97,0	9,171	19,909	929	100,0	899	96,8	10,827	20,058
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	662	92,1	18,127	25,808	711	76,5	662	93,1	17,674	25,370
WEEK 13	Postmenopausal	842	90,2	792	94,1	10,606	19,967	864	93,0	821	95,0	14,129	23,584
WEEK 25	Postmenopausal	815	87,4	779	95,6	7,617	17,124	841	90,5	795	94,5	10,021	21,199
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	8,541	17,176	921	99,1	809	87,8	10,630	20,437
FU MONTH 18	Postmenopausal	839	89,9	757	90,2	11,581	21,332	844	90,9	728	86,3	11,310	22,156
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	10,958	20,883	823	88,6	713	86,6	10,893	21,596
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	10,629	20,547	776	83,5	676	87,1	10,996	20,824
BASELINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	8	88,9	12,500	24,801
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	13,333	29,814	9	100,0	7	77,8	19,048	26,227
WEEK 13	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	9	100,0	8	88,9	16,667	25,198
WEEK 25	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	9,524	16,265
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	9	100,0	8	88,9	12,500	17,252
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	9	100,0	8	88,9	12,500	24,801
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	8	88,9	5	62,5	20,000	29,814
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	7	77,8	6	85,7	16,667	40,825
Age II													
BASELINE	< 65	1581	100,0	1544	97,7	8,722	18,790	1604	100,0	1568	97,8	9,609	19,197
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	17,098	25,006	1287	80,2	1221	94,9	18,209	26,216
WEEK 13	< 65	1497	94,7	1424	95,1	9,363	18,696	1529	95,3	1455	95,2	13,494	22,535

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1405	96,0	7,639	17,209	1501	93,6	1429	95,2	9,377	19,424
END OF TREATMENT	< 65	1569	99,2	1382	88,1	8,225	17,459	1596	99,5	1445	90,5	10,219	19,638
FU MONTH 18	< 65	1474	93,2	1313	89,1	11,602	21,423	1497	93,3	1319	88,1	10,816	20,920
FU MONTH 24	< 65	1446	91,5	1263	87,3	9,976	19,432	1450	90,4	1270	87,6	9,659	19,614
FU MONTH 36	< 65	1390	87,9	1234	88,8	9,914	20,268	1383	86,2	1200	86,8	10,139	20,601
BASELINE	>= 65	230	100,0	220	95,7	9,848	20,864	219	100,0	207	94,5	12,077	20,750
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	19,540	29,024	159	72,6	141	88,7	17,967	27,173
WEEK 13	>= 65	191	83,0	176	92,1	11,364	21,609	196	89,5	183	93,4	16,029	24,169
WEEK 25	>= 65	181	78,7	178	98,3	8,614	17,379	187	85,4	173	92,5	14,258	26,699
END OF TREATMENT	>= 65	225	97,8	189	84,0	10,229	18,547	215	98,2	183	85,1	12,933	23,369
FU MONTH 18	>= 65	189	82,2	171	90,5	14,230	24,500	191	87,2	156	81,7	14,957	24,625
FU MONTH 24	>= 65	187	81,3	170	90,9	14,902	24,328	188	85,8	156	83,0	15,171	26,597
FU MONTH 36	>= 65	181	78,7	158	87,3	13,291	22,554	173	79,0	148	85,5	15,090	24,073
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	4,301	11,359	24	100,0	24	100,0	11,111	18,822
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	19,608	23,743	17	70,8	16	94,1	12,500	23,960
WEEK 13	Grade 1	31	96,9	30	96,8	11,111	22,030	23	95,8	22	95,7	13,636	19,678
WEEK 25	Grade 1	31	96,9	29	93,5	14,943	28,986	23	95,8	22	95,7	10,606	15,891
END OF TREATMENT	Grade 1	31	96,9	27	87,1	13,580	26,569	24	100,0	22	91,7	12,121	24,224
FU MONTH 18	Grade 1	30	93,8	27	90,0	12,346	22,923	23	95,8	22	95,7	10,606	15,891
FU MONTH 24	Grade 1	28	87,5	27	96,4	13,580	24,909	23	95,8	21	91,3	9,524	18,687
FU MONTH 36	Grade 1	27	84,4	26	96,3	12,821	25,081	22	91,7	20	90,9	16,667	25,363
BASELINE	Grade 2	552	100,0	537	97,3	8,876	19,684	557	100,0	543	97,5	9,638	19,506
END OF ANTHRACYCLINE	Grade 2	445	80,6	422	94,8	18,878	26,278	446	80,1	424	95,1	16,352	25,211

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	9,416	18,451	524	94,1	504	96,2	12,169	20,315
WEEK 25	Grade 2	494	89,5	479	97,0	8,072	17,643	515	92,5	493	95,7	9,466	19,608
END OF TREATMENT	Grade 2	548	99,3	485	88,5	8,316	17,851	553	99,3	496	89,7	10,484	19,816
FU MONTH 18	Grade 2	507	91,8	457	90,1	12,181	22,184	517	92,8	448	86,7	9,598	20,668
FU MONTH 24	Grade 2	501	90,8	449	89,6	10,468	20,697	500	89,8	431	86,2	10,131	21,756
FU MONTH 36	Grade 2	487	88,2	438	89,9	10,883	22,227	476	85,5	414	87,0	9,420	20,084
BASELINE	Grade 3	1161	100,0	1133	97,6	9,032	19,155	1173	100,0	1140	97,2	9,854	19,288
END OF ANTHRACYCLINE	Grade 3	918	79,1	855	93,1	16,569	25,036	919	78,3	860	93,6	19,264	26,909
WEEK 13	Grade 3	1088	93,7	1026	94,3	9,552	19,360	1114	95,0	1052	94,4	14,322	23,800
WEEK 25	Grade 3	1059	91,2	1017	96,0	7,309	16,538	1087	92,7	1025	94,3	9,854	20,556
END OF TREATMENT	Grade 3	1150	99,1	998	86,8	8,250	17,083	1165	99,3	1050	90,1	10,159	19,756
FU MONTH 18	Grade 3	1067	91,9	946	88,7	12,051	21,751	1085	92,5	946	87,2	11,945	21,619
FU MONTH 24	Grade 3	1046	90,1	903	86,3	10,557	19,774	1053	89,8	918	87,2	9,913	19,562
FU MONTH 36	Grade 3	1002	86,3	876	87,4	10,046	19,791	999	85,2	862	86,3	10,789	21,213
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	7,937	14,311	69	100,0	68	98,6	12,255	20,688
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	17,361	26,622	64	92,8	62	96,9	17,204	25,423
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	59	95,2	10,734	16,884	64	92,8	60	93,8	17,778	23,343
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	9,195	17,431	63	91,3	62	98,4	13,978	24,553
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	10,929	18,975	69	100,0	60	87,0	16,667	25,674
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	6,790	18,744	63	91,3	59	93,7	12,994	23,987

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	9,877	19,022	62	89,9	56	90,3	17,262	26,201
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	8,333	16,000	59	85,5	52	88,1	16,667	23,338
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	7,507	18,157	715	100,0	685	95,8	10,316	20,645
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	545	92,1	18,104	25,774	572	80,0	523	91,4	18,674	27,172
WEEK 13	Breast conserving surgery	677	93,0	636	93,9	9,015	18,776	673	94,1	634	94,2	13,144	22,147
WEEK 25	Breast conserving surgery	665	91,3	638	95,9	8,046	17,463	654	91,5	614	93,9	10,966	21,690
END OF TREATMENT	Breast conserving surgery	722	99,2	624	86,4	7,959	16,433	711	99,4	623	87,6	12,092	22,124
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	11,560	21,142	659	92,2	559	84,8	12,522	23,235
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	10,822	20,444	644	90,1	555	86,2	11,592	22,565
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	10,795	21,206	616	86,2	532	86,4	11,779	22,852
BASELINE	Mastectomy	1083	100,0	1058	97,7	9,767	19,592	1107	100,0	1089	98,4	9,642	18,576
END OF ANTHRACYCLINE	Mastectomy	840	77,6	797	94,9	16,855	25,263	873	78,9	838	96,0	17,900	25,772
WEEK 13	Mastectomy	1011	93,4	964	95,4	9,959	19,214	1051	94,9	1003	95,4	14,158	23,097
WEEK 25	Mastectomy	980	90,5	945	96,4	7,549	17,069	1033	93,3	987	95,5	9,220	19,502
END OF TREATMENT	Mastectomy	1072	99,0	947	88,3	8,800	18,328	1099	99,3	1004	91,4	9,529	18,679
FU MONTH 18	Mastectomy	985	91,0	890	90,4	12,135	22,249	1028	92,9	915	89,0	10,455	20,119
FU MONTH 24	Mastectomy	967	89,3	857	88,6	10,385	19,924	993	89,7	870	87,6	9,310	18,892

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	9,960	20,116	939	84,8	816	86,9	9,967	19,782
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	7,959	17,683	665	100,0	642	96,5	10,332	19,937
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	481	92,7	17,256	25,005	523	78,6	493	94,3	19,270	27,227
WEEK 13	0 - < 2 cm	620	93,9	581	93,7	8,721	18,165	631	94,9	606	96,0	13,201	21,975
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	7,147	17,379	617	92,8	588	95,3	9,580	19,958
END OF TREATMENT	0 - < 2 cm	655	99,2	577	88,1	8,608	17,376	661	99,4	598	90,5	10,758	19,134
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	10,355	20,456	624	93,8	559	89,6	10,555	20,202
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	10,424	19,837	606	91,1	530	87,5	10,629	21,157
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	9,841	20,451	580	87,2	505	87,1	10,693	21,209
BASELINE	>= 2 - < 5 cm	1009	100,0	980	97,1	9,524	19,931	991	100,0	969	97,8	9,770	19,307
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	753	94,5	17,220	25,090	789	79,6	743	94,2	17,811	25,984
WEEK 13	>= 2 - < 5 cm	935	92,7	892	95,4	9,978	19,441	940	94,9	890	94,7	14,457	23,626
WEEK 25	>= 2 - < 5 cm	910	90,2	878	96,5	8,125	17,212	919	92,7	866	94,2	10,354	21,186
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	866	86,8	8,276	17,617	985	99,4	877	89,0	10,262	20,854

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	12,450	22,094	914	92,2	785	85,9	11,550	21,814
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	10,658	20,438	889	89,7	777	87,4	9,953	20,333
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	10,354	20,683	839	84,7	725	86,4	10,943	20,946
BASELINE	>= 5 cm	139	100,0	137	98,6	8,516	18,972	165	100,0	162	98,2	9,053	17,827
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	19,048	30,261	132	80,0	124	93,9	16,398	24,600
WEEK 13	>= 5 cm	130	93,5	124	95,4	11,022	20,261	152	92,1	140	92,1	12,143	20,076
WEEK 25	>= 5 cm	124	89,2	119	96,0	8,123	16,788	150	90,9	146	97,3	8,676	17,089
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	9,333	18,742	163	98,8	151	92,6	11,038	19,521
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	15,265	25,195	148	89,7	129	87,2	12,661	23,641
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	10,811	19,675	141	85,5	117	83,0	10,826	19,490
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	12,211	20,398	135	81,8	116	85,9	9,195	21,349
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	0,000	0,000
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
WEEK 13	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
WEEK 25	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	16,667	23,570
FU MONTH 18	Missing	3	100,0	3	100,0	22,222	38,490	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1321	98,1	8,706	18,778	1350	100,0	1311	97,1	9,636	19,306
END OF ANTHRACYCLINE	Yes	1103	81,9	1045	94,7	17,608	25,655	1104	81,8	1043	94,5	18,408	26,926
WEEK 13	Yes	1308	97,1	1239	94,7	9,335	19,178	1324	98,1	1251	94,5	13,456	22,373
WEEK 25	Yes	1277	94,8	1226	96,0	7,667	17,278	1302	96,4	1230	94,5	10,000	20,881

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1212	90,0	8,498	17,459	1350	100,0	1235	91,5	10,715	20,558
FU MONTH 18	Yes	1291	95,8	1144	88,6	11,713	21,797	1298	96,1	1131	87,1	11,288	21,482
FU MONTH 24	Yes	1266	94,0	1110	87,7	10,450	20,191	1260	93,3	1091	86,6	10,663	21,307
FU MONTH 36	Yes	1219	90,5	1062	87,1	9,824	20,125	1195	88,5	1032	86,4	10,917	21,609
BASELINE	No	464	100,0	443	95,5	9,330	19,885	473	100,0	464	98,1	10,632	19,644
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	16,498	24,830	342	72,3	319	93,3	17,450	24,197
WEEK 13	No	380	81,9	361	95,0	10,434	18,562	401	84,8	387	96,5	14,815	23,847
WEEK 25	No	368	79,3	357	97,0	8,030	17,063	386	81,6	372	96,4	9,588	18,657
END OF TREATMENT	No	447	96,3	359	80,3	8,357	18,090	461	97,5	393	85,2	9,924	18,609
FU MONTH 18	No	372	80,2	340	91,4	12,549	21,861	390	82,5	344	88,2	11,143	21,032
FU MONTH 24	No	367	79,1	323	88,0	10,939	19,939	378	79,9	335	88,6	8,955	17,854
FU MONTH 36	No	352	75,9	330	93,8	11,818	21,862	361	76,3	316	87,5	9,916	19,157
Race													
BASELINE	White	1252	100,0	1208	96,5	8,140	19,068	1255	100,0	1214	96,7	9,418	19,000
END OF ANTHRACYCLINE	White	1010	80,7	930	92,1	17,455	25,833	1018	81,1	941	92,4	18,526	27,209
WEEK 13	White	1158	92,5	1079	93,2	8,279	18,705	1183	94,3	1098	92,8	13,692	23,382
WEEK 25	White	1120	89,5	1061	94,7	6,817	16,966	1150	91,6	1072	93,2	9,701	21,003
END OF TREATMENT	White	1238	98,9	1046	84,5	7,808	17,243	1244	99,1	1088	87,5	10,754	20,862
FU MONTH 18	White	1138	90,9	980	86,1	12,007	22,895	1152	91,8	966	83,9	11,456	22,196
FU MONTH 24	White	1115	89,1	943	84,6	10,887	20,930	1120	89,2	941	84,0	10,131	21,224
FU MONTH 36	White	1071	85,5	923	86,2	10,076	20,790	1064	84,8	896	84,2	10,528	21,537
BASELINE	Black	25	100,0	24	96,0	4,167	11,261	31	100,0	30	96,8	20,000	31,073
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	7,407	14,699	15	48,4	15	100,0	24,444	36,659
WEEK 13	Black	21	84,0	17	81,0	7,843	18,743	29	93,5	28	96,6	26,190	34,375

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	8,772	15,080	29	93,5	28	96,6	19,048	29,297
END OF TREATMENT	Black	24	96,0	22	91,7	16,667	24,667	31	100,0	28	90,3	19,048	27,857
FU MONTH 18	Black	23	92,0	17	73,9	9,804	19,596	29	93,5	24	82,8	15,278	24,035
FU MONTH 24	Black	22	88,0	18	81,8	14,815	20,523	28	90,3	23	82,1	11,594	19,092
FU MONTH 36	Black	22	88,0	18	81,8	7,407	14,260	26	83,9	20	76,9	13,333	27,359
BASELINE	Asian	477	100,0	475	99,6	10,737	19,470	484	100,0	480	99,2	10,556	19,733
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	17,821	25,081	375	77,5	368	98,1	17,029	23,342
WEEK 13	Asian	455	95,4	450	98,9	12,370	19,712	466	96,3	465	99,8	13,118	19,996
WEEK 25	Asian	450	94,3	449	99,8	9,428	17,329	465	96,1	459	98,7	9,731	18,223
END OF TREATMENT	Asian	475	99,6	452	95,2	9,808	18,296	484	100,0	464	95,9	9,555	17,991
FU MONTH 18	Asian	447	93,7	434	97,1	12,135	19,781	461	95,2	444	96,3	10,511	19,516
FU MONTH 24	Asian	442	92,7	423	95,7	10,165	18,899	445	91,9	421	94,6	10,768	19,387
FU MONTH 36	Asian	424	88,9	402	94,8	11,443	20,832	425	87,8	397	93,4	11,083	19,827
BASELINE	Other	52	100,0	52	100,0	10,256	15,535	51	100,0	50	98,0	9,333	15,119
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	12,613	21,302	36	70,6	36	100,0	19,444	26,874
WEEK 13	Other	49	94,2	49	100,0	14,286	18,002	45	88,2	45	100,0	15,556	23,138
WEEK 25	Other	49	94,2	49	100,0	12,245	21,185	42	82,4	41	97,6	11,382	19,163
END OF TREATMENT	Other	52	100,0	47	90,4	5,674	12,663	50	98,0	47	94,0	9,929	15,409
FU MONTH 18	Other	50	96,2	48	96,0	9,722	18,138	44	86,3	39	88,6	12,821	19,669
FU MONTH 24	Other	49	94,2	45	91,8	6,667	13,484	43	84,3	39	90,7	7,692	17,871
FU MONTH 36	Other	49	94,2	44	89,8	6,061	14,860	39	76,5	33	84,6	9,091	19,135
BASELINE	Missing	5	100,0	5	100,0	13,333	29,814	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	20,000	29,814	2	100,0	2	100,0	0,000	0,000
WEEK 13	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	16,667	19,245	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC07_SG.xls
11AUG2020 16:16

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Diarrhea Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1757	97,0	5,293	14,596	1823	100,0	1776	97,4	5,143	13,834
END OF ANTHRACYCLINE	n/a	1432	79,1	1338	93,4	9,666	19,155	1446	79,3	1359	94,0	8,438	17,041
WEEK 13	n/a	1688	93,2	1603	95,0	26,908	28,843	1725	94,6	1637	94,9	14,457	22,449
WEEK 25	n/a	1645	90,8	1580	96,0	17,848	25,208	1688	92,6	1601	94,8	8,182	17,844
END OF TREATMENT	n/a	1794	99,1	1570	87,5	15,796	24,323	1811	99,3	1624	89,7	7,061	16,939
FU MONTH 18	n/a	1663	91,8	1479	88,9	4,350	12,796	1688	92,6	1472	87,2	5,389	14,478
FU MONTH 24	n/a	1633	90,2	1431	87,6	4,356	12,972	1638	89,9	1421	86,8	5,255	14,714
FU MONTH 36	n/a	1571	86,7	1391	88,5	3,858	11,806	1556	85,4	1349	86,7	5,238	14,317
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	1,361	6,664	43	100,0	40	93,0	4,167	13,477
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	12,903	18,614	26	60,5	25	96,2	9,333	18,053
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	19,697	25,231	40	93,0	39	97,5	11,966	16,199
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	15,504	25,561	38	88,4	35	92,1	8,571	16,848
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	17,424	27,364	42	97,7	37	88,1	3,604	10,493
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	3,876	10,812	39	90,7	36	92,3	4,630	11,691

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	3,175	9,903	39	90,7	34	87,2	4,902	18,591
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	3,704	10,594	39	90,7	37	94,9	4,505	11,553
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	6,217	14,912	278	100,0	271	97,5	4,551	13,448
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	9,176	20,279	203	73,0	190	93,6	8,772	17,625
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	26,525	28,925	263	94,6	253	96,2	15,152	22,686
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	20,394	27,471	256	92,1	246	96,1	10,434	20,304
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	16,006	24,757	276	99,3	255	92,4	9,281	19,309
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	3,976	11,736	259	93,2	233	90,0	6,438	16,128
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	5,582	14,459	256	92,1	229	89,5	6,550	16,835
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	3,101	10,722	251	90,3	227	90,4	5,286	15,086
BASELINE	1-3 positive nodes	907	100,0	883	97,4	5,021	14,151	900	100,0	876	97,3	5,251	13,346
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	657	92,1	9,843	19,596	707	78,6	666	94,2	8,358	16,408
WEEK 13	1-3 positive nodes	847	93,4	802	94,7	26,850	28,454	854	94,9	804	94,1	13,972	22,124
WEEK 25	1-3 positive nodes	825	91,0	785	95,2	18,132	25,553	836	92,9	790	94,5	7,046	16,686
END OF TREATMENT	1-3 positive nodes	899	99,1	780	86,8	15,427	23,943	897	99,7	810	90,3	6,584	16,507
FU MONTH 18	1-3 positive nodes	838	92,4	735	87,7	4,036	12,561	852	94,7	742	87,1	5,166	13,918

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	4,310	12,966	830	92,2	725	87,3	4,690	13,090
FU MONTH 36	1-3 positive nodes	804	88,6	704	87,6	4,261	12,477	794	88,2	666	83,9	5,105	13,945
BASELINE	>= 4 positive nodes	596	100,0	573	96,1	5,643	15,556	602	100,0	589	97,8	5,320	14,741
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	9,393	18,142	510	84,7	478	93,7	8,368	17,659
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	27,778	29,660	568	94,4	541	95,2	15,034	23,216
WEEK 25	>= 4 positive nodes	533	89,4	515	96,6	16,440	23,466	558	92,7	530	95,0	8,805	18,276
END OF TREATMENT	>= 4 positive nodes	590	99,0	519	88,0	16,121	24,490	596	99,0	522	87,6	6,960	16,666
FU MONTH 18	>= 4 positive nodes	533	89,4	483	90,6	5,038	13,746	538	89,4	461	85,7	5,278	14,698
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	3,974	12,500	513	85,2	433	84,4	5,543	15,716
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	3,591	11,310	472	78,4	419	88,8	5,489	14,731
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1400	97,3	4,857	13,929	1448	100,0	1411	97,4	4,796	13,457
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1336	93,5	9,681	19,165	1444	99,7	1358	94,0	8,370	16,865
WEEK 13	Anthracycline containing regimen	1347	93,6	1288	95,6	25,958	28,243	1374	94,9	1302	94,8	13,415	21,774
WEEK 25	Anthracycline containing regimen	1311	91,1	1255	95,7	17,875	25,295	1346	93,0	1276	94,8	7,941	17,653
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1255	87,8	15,564	24,481	1444	99,7	1299	90,0	7,108	17,058

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1180	88,8	4,294	13,040	1340	92,5	1176	87,8	5,385	14,661
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1145	87,7	4,425	13,142	1308	90,3	1133	86,6	5,296	15,136
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1110	88,2	3,904	11,876	1244	85,9	1083	87,1	5,078	14,326
BASELINE	Non-anthracycline containing regimen	372	100,0	357	96,0	7,003	16,875	375	100,0	365	97,3	6,484	15,150
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	0,000	0,000	2	0,5	1	50,0	100,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	30,794	30,920	351	93,6	335	95,4	18,507	24,520
WEEK 25	Non-anthracycline containing regimen	334	89,8	325	97,3	17,744	24,908	342	91,2	325	95,0	9,128	18,577
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	16,720	23,701	367	97,9	325	88,6	6,872	16,479
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	4,571	11,805	348	92,8	296	85,1	5,405	13,753
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	4,079	12,286	330	88,0	288	87,3	5,093	12,944
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	3,677	11,544	312	83,2	266	85,3	5,890	14,289
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	839	97,1	5,602	14,715	858	100,0	839	97,8	4,728	13,533
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	636	94,6	9,801	19,799	661	77,0	619	93,6	8,508	17,670
WEEK 13	Negative (ER and PgR negative)	815	94,3	773	94,8	25,399	28,192	804	93,7	773	96,1	14,015	22,327
WEEK 25	Negative (ER and PgR negative)	799	92,5	771	96,5	18,634	25,989	786	91,6	750	95,4	8,978	19,010
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	16,601	24,828	854	99,5	763	89,3	7,471	17,444
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	715	89,3	4,196	12,265	781	91,0	694	88,9	5,476	14,172
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	693	88,1	5,002	14,019	763	88,9	674	88,3	5,836	15,491
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	3,644	11,744	735	85,7	654	89,0	5,403	14,573
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	5,011	14,489	965	100,0	937	97,1	5,514	14,095
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	702	92,4	9,544	18,565	785	81,3	740	94,3	8,378	16,508
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	830	95,1	28,313	29,383	921	95,4	864	93,8	14,853	22,564
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	809	95,6	17,099	24,433	902	93,5	851	94,3	7,481	16,731
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	807	86,0	15,035	23,827	957	99,2	861	90,0	6,698	16,481
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	764	88,6	4,494	13,280	907	94,0	778	85,8	5,313	14,755
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	3,749	11,883	875	90,7	747	85,4	4,730	13,966

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	4,062	11,869	821	85,1	695	84,7	5,084	14,080
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	6,848	17,160	260	100,0	255	98,1	6,667	15,198
END OF ANTHRACYCLINE	USA/Canada	109	41,1	101	92,7	8,581	15,386	111	42,7	104	93,7	11,859	18,532
WEEK 13	USA/Canada	242	91,3	229	94,6	34,643	30,320	236	90,8	224	94,9	16,964	23,621
WEEK 25	USA/Canada	234	88,3	224	95,7	22,024	27,175	230	88,5	219	95,2	9,741	18,793
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	18,673	24,822	255	98,1	229	89,8	8,151	19,535
FU MONTH 18	USA/Canada	238	89,8	193	81,1	5,009	13,744	231	88,8	180	77,9	6,111	14,301
FU MONTH 24	USA/Canada	231	87,2	188	81,4	4,610	13,441	224	86,2	177	79,0	3,955	11,379
FU MONTH 36	USA/Canada	223	84,2	180	80,7	3,889	12,345	205	78,8	156	76,1	5,128	14,740
BASELINE	Western Europe	827	100,0	785	94,9	5,011	14,690	822	100,0	785	95,5	5,223	14,272
END OF ANTHRACYCLINE	Western Europe	732	88,5	661	90,3	11,498	21,686	728	88,6	661	90,8	9,228	18,638
WEEK 13	Western Europe	764	92,4	696	91,1	29,262	30,624	778	94,6	708	91,0	14,360	23,574
WEEK 25	Western Europe	738	89,2	691	93,6	20,646	27,479	750	91,2	680	90,7	8,578	18,712
END OF TREATMENT	Western Europe	821	99,3	690	84,0	19,710	27,728	817	99,4	700	85,7	7,857	18,620
FU MONTH 18	Western Europe	754	91,2	645	85,5	4,496	13,477	764	92,9	630	82,5	6,032	16,244
FU MONTH 24	Western Europe	739	89,4	612	82,8	4,575	14,045	747	90,9	616	82,5	6,331	17,565
FU MONTH 36	Western Europe	713	86,2	613	86,0	4,676	13,334	712	86,6	594	83,4	5,612	15,314
BASELINE	Asia Pacific	490	100,0	487	99,4	4,860	12,344	512	100,0	508	99,2	4,593	12,417
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	8,467	16,086	397	77,5	390	98,2	7,778	14,904
WEEK 13	Asia Pacific	466	95,1	465	99,8	22,294	25,096	493	96,3	492	99,8	14,160	19,741
WEEK 25	Asia Pacific	461	94,1	460	99,8	13,841	20,856	492	96,1	488	99,2	6,694	14,977

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	10,848	18,709	512	100,0	490	95,7	5,782	13,335
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	4,952	13,057	485	94,7	470	96,9	3,901	10,945
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	4,384	11,931	470	91,8	447	95,1	5,071	12,593
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	3,277	9,937	453	88,5	432	95,4	4,552	12,327
BASELINE	Latin America	43	100,0	43	100,0	2,326	8,592	47	100,0	46	97,9	6,522	15,104
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	6,897	20,662	32	68,1	32	100,0	7,292	18,422
WEEK 13	Latin America	40	93,0	40	100,0	24,167	25,021	44	93,6	44	100,0	18,182	30,882
WEEK 25	Latin America	39	90,7	39	100,0	10,256	20,454	44	93,6	44	100,0	5,303	14,275
END OF TREATMENT	Latin America	42	97,7	38	90,5	7,895	16,319	45	95,7	42	93,3	3,968	10,926
FU MONTH 18	Latin America	41	95,3	37	90,2	1,802	7,641	42	89,4	40	95,2	4,167	11,164
FU MONTH 24	Latin America	40	93,0	36	90,0	0,926	5,556	41	87,2	39	95,1	0,855	5,338
FU MONTH 36	Latin America	38	88,4	34	89,5	0,980	5,717	37	78,7	36	97,3	3,704	10,624
BASELINE	Other	186	100,0	184	98,9	6,159	16,661	182	100,0	182	100,0	3,846	13,245
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	6,358	15,812	178	97,8	172	96,6	5,039	13,015
WEEK 13	Other	176	94,6	173	98,3	20,231	26,324	174	95,6	169	97,1	11,440	20,589
WEEK 25	Other	173	93,0	166	96,0	13,454	22,013	172	94,5	170	98,8	9,608	20,969
END OF TREATMENT	Other	185	99,5	162	87,6	11,317	20,063	182	100,0	163	89,6	6,748	16,212
FU MONTH 18	Other	171	91,9	153	89,5	1,743	7,445	166	91,2	152	91,6	6,798	16,870
FU MONTH 24	Other	169	90,9	154	91,1	3,896	12,020	156	85,7	142	91,0	3,991	12,225
FU MONTH 36	Other	160	86,0	147	91,9	2,721	9,954	149	81,9	131	87,9	6,361	16,074
Protocol version													
BASELINE	Protocol A	1240	100,0	1204	97,1	5,343	14,766	1246	100,0	1210	97,1	5,372	14,076

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	913	92,8	9,931	19,589	988	79,3	927	93,8	8,846	17,822
WEEK 13	Protocol A	1155	93,1	1105	95,7	26,727	28,474	1180	94,7	1113	94,3	15,094	22,569
WEEK 25	Protocol A	1125	90,7	1082	96,2	17,714	25,395	1157	92,9	1092	94,4	9,158	18,487
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	15,906	24,596	1236	99,2	1114	90,1	7,451	17,113
FU MONTH 18	Protocol A	1142	92,1	1022	89,5	4,534	13,117	1156	92,8	1003	86,8	5,417	14,226
FU MONTH 24	Protocol A	1124	90,6	994	88,4	4,963	14,111	1127	90,4	978	86,8	5,692	15,618
FU MONTH 36	Protocol A	1087	87,7	980	90,2	3,810	12,015	1069	85,8	932	87,2	5,722	15,237
BASELINE	Protocol Amendment B	571	100,0	553	96,8	5,184	14,232	577	100,0	566	98,1	4,653	13,302
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	425	94,9	9,098	18,196	458	79,4	432	94,3	7,562	15,213
WEEK 13	Protocol Amendment B	533	93,3	498	93,4	27,309	29,669	545	94,5	524	96,1	13,104	22,154
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	18,139	24,819	531	92,0	509	95,9	6,090	16,201
END OF TREATMENT	Protocol Amendment B	565	98,9	497	88,0	15,560	23,746	575	99,7	510	88,7	6,209	16,539
FU MONTH 18	Protocol Amendment B	521	91,2	457	87,7	3,939	12,053	532	92,2	469	88,2	5,330	15,019
FU MONTH 24	Protocol Amendment B	509	89,1	437	85,9	2,975	9,778	511	88,6	443	86,7	4,289	12,451
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	3,974	11,305	487	84,4	417	85,6	4,157	11,956
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	5,426	14,014	321	100,0	311	96,9	4,502	13,431
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	9,729	20,042	229	71,3	215	93,9	8,837	17,634
WEEK 13	0 positive nodes	294	95,5	279	94,9	25,448	28,441	303	94,4	292	96,4	14,726	21,935
WEEK 25	0 positive nodes	287	93,2	280	97,6	19,643	27,200	294	91,6	281	95,6	10,202	19,889
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	16,236	25,150	318	99,1	292	91,8	8,562	18,510
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	3,959	11,569	298	92,8	269	90,3	6,196	15,601

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	251	86,6	5,179	13,815	295	91,9	263	89,2	6,337	17,043
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	3,205	10,682	290	90,3	264	91,0	5,177	14,626
BASELINE	>= 1 positive nodes	1503	100,0	1456	96,9	5,266	14,718	1502	100,0	1465	97,5	5,279	13,919
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1129	93,4	9,655	18,995	1217	81,0	1144	94,0	8,362	16,934
WEEK 13	>= 1 positive nodes	1394	92,7	1324	95,0	27,216	28,928	1422	94,7	1345	94,6	14,399	22,567
WEEK 25	>= 1 positive nodes	1358	90,4	1300	95,7	17,462	24,752	1394	92,8	1320	94,7	7,753	17,356
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1299	87,2	15,704	24,156	1493	99,4	1332	89,2	6,732	16,564
FU MONTH 18	>= 1 positive nodes	1371	91,2	1218	88,8	4,433	13,047	1390	92,5	1203	86,5	5,209	14,216
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	4,181	12,785	1343	89,4	1158	86,2	5,009	14,128
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	4,008	12,049	1266	84,3	1085	85,7	5,253	14,248
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	4,807	13,477	885	100,0	868	98,1	4,877	12,928
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	9,432	18,110	726	82,0	692	95,3	8,141	16,423
WEEK 13	Premenopausal	841	96,3	806	95,8	25,931	27,584	852	96,3	809	95,0	13,968	21,780
WEEK 25	Premenopausal	825	94,5	797	96,6	17,775	25,460	838	94,7	800	95,5	6,875	16,800
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	14,985	23,253	881	99,5	809	91,8	6,180	15,741
FU MONTH 18	Premenopausal	819	93,8	723	88,3	3,827	11,602	835	94,4	736	88,1	4,529	13,379
FU MONTH 24	Premenopausal	803	92,0	705	87,8	3,924	11,598	807	91,2	705	87,4	4,350	13,647

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	3,423	11,647	773	87,3	667	86,3	4,048	12,467
BASELINE	Postmenopausal	933	100,0	899	96,4	5,784	15,610	929	100,0	900	96,9	5,296	14,336
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	658	91,5	9,929	20,214	711	76,5	660	92,8	8,586	17,528
WEEK 13	Postmenopausal	842	90,2	793	94,2	28,037	30,057	864	93,0	820	94,9	14,919	23,142
WEEK 25	Postmenopausal	815	87,4	778	95,5	18,038	25,003	841	90,5	794	94,4	9,488	18,778
END OF TREATMENT	Postmenopausal	923	98,9	803	87,0	16,646	25,320	921	99,1	807	87,6	7,848	17,932
FU MONTH 18	Postmenopausal	839	89,9	753	89,7	4,869	13,856	844	90,9	728	86,3	6,227	15,470
FU MONTH 24	Postmenopausal	825	88,4	722	87,5	4,801	14,210	823	88,6	711	86,4	6,001	15,370
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	4,289	11,976	776	83,5	676	87,1	6,213	15,635
BASELINE	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	8	88,9	16,667	35,635
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	23,810	25,198
WEEK 13	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	9	100,0	8	88,9	16,667	17,817
WEEK 25	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	7	77,8	9,524	16,265
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	9	100,0	8	88,9	16,667	25,198
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	9	100,0	8	88,9	8,333	15,430
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	8	88,9	5	62,5	26,667	36,515
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	7	77,8	6	85,7	27,778	25,092
Age II													
BASELINE	< 65	1581	100,0	1541	97,5	5,148	14,143	1604	100,0	1568	97,8	4,996	13,520
END OF ANTHRACYCLINE	< 65	1268	80,2	1193	94,1	9,584	18,929	1287	80,2	1218	94,6	8,566	17,108
WEEK 13	< 65	1497	94,7	1425	95,2	26,316	28,416	1529	95,3	1453	95,0	14,384	22,310

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	17,700	25,233	1501	93,6	1428	95,1	7,913	17,393
END OF TREATMENT	< 65	1569	99,2	1382	88,1	15,605	23,835	1596	99,5	1441	90,3	6,916	16,735
FU MONTH 18	< 65	1474	93,2	1309	88,8	4,278	12,719	1497	93,3	1316	87,9	5,344	14,334
FU MONTH 24	< 65	1446	91,5	1262	87,3	4,200	12,558	1450	90,4	1266	87,3	5,240	14,869
FU MONTH 36	< 65	1390	87,9	1233	88,7	3,677	11,436	1383	86,2	1201	86,8	5,107	14,004
BASELINE	>= 65	230	100,0	216	93,9	6,327	17,494	219	100,0	208	95,0	6,250	15,999
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	10,345	20,978	159	72,6	141	88,7	7,329	16,471
WEEK 13	>= 65	191	83,0	178	93,2	31,648	31,746	196	89,5	184	93,9	15,036	23,578
WEEK 25	>= 65	181	78,7	177	97,8	19,021	25,046	187	85,4	173	92,5	10,405	21,135
END OF TREATMENT	>= 65	225	97,8	188	83,6	17,199	27,680	215	98,2	183	85,1	8,197	18,479
FU MONTH 18	>= 65	189	82,2	170	89,9	4,902	13,403	191	87,2	156	81,7	5,769	15,687
FU MONTH 24	>= 65	187	81,3	169	90,4	5,523	15,719	188	85,8	155	82,4	5,376	13,422
FU MONTH 36	>= 65	181	78,7	158	87,3	5,274	14,337	173	79,0	148	85,5	6,306	16,656
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	3,226	13,207	24	100,0	24	100,0	1,389	6,804
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	7,843	14,575	17	70,8	16	94,1	8,333	19,245
WEEK 13	Grade 1	31	96,9	30	96,8	23,333	27,889	23	95,8	22	95,7	18,182	19,860
WEEK 25	Grade 1	31	96,9	28	90,3	19,048	30,670	23	95,8	22	95,7	6,061	13,159
END OF TREATMENT	Grade 1	31	96,9	27	87,1	11,111	26,149	24	100,0	22	91,7	7,576	14,298
FU MONTH 18	Grade 1	30	93,8	27	90,0	6,173	16,111	23	95,8	22	95,7	3,030	9,808
FU MONTH 24	Grade 1	28	87,5	27	96,4	11,111	20,672	23	95,8	21	91,3	3,175	10,026
FU MONTH 36	Grade 1	27	84,4	26	96,3	3,846	10,860	22	91,7	20	90,9	6,667	17,438
BASELINE	Grade 2	552	100,0	535	96,9	4,424	13,499	557	100,0	543	97,5	5,279	13,762
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	8,117	17,620	446	80,1	424	95,1	8,097	15,878

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	26,200	28,306	524	94,1	503	96,0	14,248	22,321
WEEK 25	Grade 2	494	89,5	478	96,8	16,388	24,490	515	92,5	492	95,5	7,927	17,874
END OF TREATMENT	Grade 2	548	99,3	485	88,5	14,502	23,336	553	99,3	494	89,3	6,073	14,983
FU MONTH 18	Grade 2	507	91,8	455	89,7	3,956	12,670	517	92,8	448	86,7	5,134	14,821
FU MONTH 24	Grade 2	501	90,8	449	89,6	3,786	12,521	500	89,8	431	86,2	5,027	14,305
FU MONTH 36	Grade 2	487	88,2	437	89,7	3,738	11,893	476	85,5	413	86,8	4,681	13,725
BASELINE	Grade 3	1161	100,0	1128	97,2	5,733	15,079	1173	100,0	1141	97,3	5,171	14,016
END OF ANTHRACYCLINE	Grade 3	918	79,1	850	92,6	10,471	19,983	919	78,3	858	93,4	8,625	17,364
WEEK 13	Grade 3	1088	93,7	1027	94,4	27,556	29,382	1114	95,0	1052	94,4	14,195	22,508
WEEK 25	Grade 3	1059	91,2	1016	95,9	18,537	25,517	1087	92,7	1025	94,3	8,293	18,089
END OF TREATMENT	Grade 3	1150	99,1	997	86,7	16,817	24,888	1165	99,3	1048	90,0	7,538	17,944
FU MONTH 18	Grade 3	1067	91,9	944	88,5	4,555	12,906	1085	92,5	944	87,0	5,473	14,464
FU MONTH 24	Grade 3	1046	90,1	901	86,1	4,514	13,028	1053	89,8	913	86,7	5,367	15,107
FU MONTH 36	Grade 3	1002	86,3	876	87,4	3,995	11,948	999	85,2	865	86,6	5,356	14,463
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	5,820	15,310	69	100,0	68	98,6	4,902	13,214
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	9,722	18,138	64	92,8	61	95,3	8,197	19,866
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	60	96,8	23,333	24,006	64	92,8	60	93,8	19,444	23,201
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	17,241	22,721	63	91,3	62	98,4	9,140	14,992
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	11,475	20,981	69	100,0	60	87,0	6,667	14,780
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	53	89,8	3,145	9,837	63	91,3	58	92,1	6,897	13,621

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	3,086	9,753	62	89,9	56	90,3	5,952	12,882
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	2,564	8,969	59	85,5	51	86,4	7,190	15,368
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	702	96,4	5,271	14,652	715	100,0	685	95,8	4,915	13,374
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	540	91,2	9,753	19,251	572	80,0	522	91,3	8,685	17,919
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	29,199	30,862	673	94,1	632	93,9	14,926	22,452
WEEK 25	Breast conserving surgery	665	91,3	637	95,8	19,362	25,870	654	91,5	614	93,9	8,849	18,642
END OF TREATMENT	Breast conserving surgery	722	99,2	622	86,1	17,203	25,497	711	99,4	622	87,5	6,645	16,452
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	4,103	12,557	659	92,2	558	84,7	5,735	15,439
FU MONTH 24	Breast conserving surgery	666	91,5	574	86,2	4,762	13,945	644	90,1	553	85,9	5,847	15,925
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	4,389	12,764	616	86,2	534	86,7	5,306	14,968
BASELINE	Mastectomy	1083	100,0	1055	97,4	5,308	14,565	1107	100,0	1090	98,5	5,291	14,125
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	9,607	19,101	873	78,9	836	95,8	8,293	16,486
WEEK 13	Mastectomy	1011	93,4	966	95,5	25,397	27,341	1051	94,9	1004	95,5	14,177	22,461
WEEK 25	Mastectomy	980	90,5	943	96,2	16,826	24,712	1033	93,3	986	95,5	7,776	17,333
END OF TREATMENT	Mastectomy	1072	99,0	948	88,4	14,873	23,489	1099	99,3	1001	91,1	7,326	17,245
FU MONTH 18	Mastectomy	985	91,0	886	89,9	4,515	12,958	1028	92,9	913	88,8	5,184	13,871
FU MONTH 24	Mastectomy	967	89,3	857	88,6	4,084	12,278	993	89,7	867	87,3	4,883	13,891

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	3,498	11,103	939	84,8	815	86,8	5,194	13,884
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	643	97,4	4,925	14,228	665	100,0	641	96,4	4,888	13,579
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	480	92,5	8,194	17,298	523	78,6	491	93,9	7,943	15,730
WEEK 13	0 - < 2 cm	620	93,9	582	93,9	26,346	29,088	631	94,9	605	95,9	14,160	21,352
WEEK 25	0 - < 2 cm	608	92,1	580	95,4	19,368	26,689	617	92,8	588	95,3	7,993	17,896
END OF TREATMENT	0 - < 2 cm	655	99,2	575	87,8	17,043	25,942	661	99,4	596	90,2	6,432	15,867
FU MONTH 18	0 - < 2 cm	617	93,5	543	88,0	4,297	11,891	624	93,8	559	89,6	4,413	11,991
FU MONTH 24	0 - < 2 cm	607	92,0	532	87,6	4,261	13,203	606	91,1	529	87,3	4,537	13,152
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	4,762	13,369	580	87,2	506	87,2	4,611	13,127
BASELINE	>= 2 - < 5 cm	1009	100,0	975	96,6	5,504	15,045	991	100,0	970	97,9	5,086	13,855
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	750	94,1	10,667	20,205	789	79,6	742	94,0	8,760	17,735
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	27,151	28,797	940	94,9	890	94,7	14,831	23,177
WEEK 25	>= 2 - < 5 cm	910	90,2	879	96,6	16,875	24,329	919	92,7	866	94,2	8,507	18,084
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	867	86,9	14,802	23,270	985	99,4	875	88,8	7,048	17,317

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	826	89,5	4,116	12,892	914	92,2	781	85,4	6,103	16,138
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	4,119	12,430	889	89,7	774	87,1	5,642	15,670
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	3,237	10,727	839	84,7	726	86,5	5,785	15,169
BASELINE	>= 5 cm	139	100,0	137	98,6	5,596	13,142	165	100,0	163	98,8	6,339	14,606
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	9,206	19,335	132	80,0	124	93,9	8,333	17,845
WEEK 13	>= 5 cm	130	93,5	123	94,6	27,100	27,444	152	92,1	140	92,1	13,571	22,582
WEEK 25	>= 5 cm	124	89,2	118	95,2	17,232	23,764	150	90,9	145	96,7	7,126	16,286
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	16,800	23,806	163	98,8	151	92,6	9,272	18,119
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	6,231	15,947	148	89,7	130	87,8	4,872	12,528
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	6,607	15,453	141	85,5	116	82,3	6,034	14,971
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	3,630	10,436	135	81,8	115	85,2	4,638	13,883
BASELINE	Missing	3	100,0	2	66,7	0,000	0,000	2	100,0	2	100,0	16,667	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	3	100,0	3	100,0	55,556	50,918	2	100,0	2	100,0	0,000	0,000
WEEK 25	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	33,333	47,140
FU MONTH 18	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	33,333	47,140
FU MONTH 24	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	3	100,0	3	100,0	11,111	19,245	2	100,0	2	100,0	0,000	0,000
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1316	97,7	5,041	13,785	1350	100,0	1312	97,2	5,056	13,742
END OF ANTHRACYCLINE	Yes	1103	81,9	1041	94,4	9,766	18,993	1104	81,8	1040	94,2	8,462	17,148
WEEK 13	Yes	1308	97,1	1241	94,9	27,451	29,182	1324	98,1	1249	94,3	14,065	22,141
WEEK 25	Yes	1277	94,8	1223	95,8	18,016	25,296	1302	96,4	1229	94,4	7,974	17,736

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1210	89,8	16,391	24,599	1350	100,0	1232	91,3	7,089	17,108
FU MONTH 18	Yes	1291	95,8	1140	88,3	4,415	13,066	1298	96,1	1130	87,1	5,575	14,894
FU MONTH 24	Yes	1266	94,0	1108	87,5	4,332	13,035	1260	93,3	1086	86,2	5,279	15,036
FU MONTH 36	Yes	1219	90,5	1062	87,1	4,080	12,284	1195	88,5	1033	86,4	5,034	14,244
BASELINE	No	464	100,0	441	95,0	6,047	16,779	473	100,0	464	98,1	5,388	14,103
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	9,315	19,740	342	72,3	319	93,3	8,359	16,712
WEEK 13	No	380	81,9	362	95,3	25,046	27,607	401	84,8	388	96,8	15,722	23,398
WEEK 25	No	368	79,3	357	97,0	17,274	24,930	386	81,6	372	96,4	8,871	18,204
END OF TREATMENT	No	447	96,3	360	80,5	13,796	23,295	461	97,5	392	85,0	6,973	16,417
FU MONTH 18	No	372	80,2	339	91,1	4,130	11,861	390	82,5	342	87,7	4,776	13,014
FU MONTH 24	No	367	79,1	323	88,0	4,438	12,772	378	79,9	335	88,6	5,174	13,640
FU MONTH 36	No	352	75,9	329	93,5	3,141	10,094	361	76,3	316	87,5	5,907	14,557
Race													
BASELINE	White	1252	100,0	1202	96,0	5,380	15,107	1255	100,0	1215	96,8	5,240	14,092
END OF ANTHRACYCLINE	White	1010	80,7	926	91,7	10,475	20,666	1018	81,1	938	92,1	8,564	17,730
WEEK 13	White	1158	92,5	1082	93,4	29,144	30,565	1183	94,3	1097	92,7	14,646	23,009
WEEK 25	White	1120	89,5	1061	94,7	20,138	26,771	1150	91,6	1071	93,1	8,777	18,783
END OF TREATMENT	White	1238	98,9	1045	84,4	18,278	26,115	1244	99,1	1085	87,2	7,742	18,265
FU MONTH 18	White	1138	90,9	977	85,9	4,299	13,230	1152	91,8	966	83,9	6,039	15,745
FU MONTH 24	White	1115	89,1	941	84,4	4,286	13,379	1120	89,2	937	83,7	5,301	15,535
FU MONTH 36	White	1071	85,5	923	86,2	4,045	12,536	1064	84,8	896	84,2	5,543	15,041
BASELINE	Black	25	100,0	24	96,0	2,778	9,411	31	100,0	30	96,8	5,556	15,371
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	7,407	14,699	15	48,4	15	100,0	4,444	11,729
WEEK 13	Black	21	84,0	17	81,0	35,294	32,212	29	93,5	28	96,6	21,429	30,381

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	18	85,7	11,111	19,803	29	93,5	28	96,6	9,524	23,757
END OF TREATMENT	Black	24	96,0	22	91,7	7,576	14,298	31	100,0	28	90,3	9,524	23,757
FU MONTH 18	Black	23	92,0	17	73,9	5,882	13,098	29	93,5	24	82,8	9,722	18,334
FU MONTH 24	Black	22	88,0	18	81,8	5,556	12,783	28	90,3	23	82,1	4,348	11,478
FU MONTH 36	Black	22	88,0	18	81,8	1,852	7,857	26	83,9	20	76,9	6,667	23,195
BASELINE	Asian	477	100,0	474	99,4	5,415	13,751	484	100,0	480	99,2	4,861	13,083
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	8,126	15,371	375	77,5	368	98,1	8,152	15,168
WEEK 13	Asian	455	95,4	450	98,9	22,074	24,302	466	96,3	465	99,8	13,333	19,427
WEEK 25	Asian	450	94,3	448	99,6	13,170	20,500	465	96,1	459	98,7	6,899	15,208
END OF TREATMENT	Asian	475	99,6	452	95,2	10,841	18,913	484	100,0	463	95,7	5,400	12,868
FU MONTH 18	Asian	447	93,7	433	96,9	4,465	11,810	461	95,2	441	95,7	3,930	11,222
FU MONTH 24	Asian	442	92,7	423	95,7	4,728	12,515	445	91,9	420	94,4	5,556	13,461
FU MONTH 36	Asian	424	88,9	401	94,6	3,741	10,534	425	87,8	398	93,6	4,523	12,142
BASELINE	Other	52	100,0	52	100,0	3,846	12,618	51	100,0	50	98,0	5,333	14,062
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	4,505	11,553	36	70,6	36	100,0	9,259	18,875
WEEK 13	Other	49	94,2	49	100,0	19,728	19,147	45	88,2	45	100,0	17,037	30,668
WEEK 25	Other	49	94,2	48	98,0	12,500	22,413	42	82,4	41	97,6	6,504	15,311
END OF TREATMENT	Other	52	100,0	47	90,4	11,348	22,281	50	98,0	47	94,0	6,383	14,969
FU MONTH 18	Other	50	96,2	47	94,0	4,255	13,219	44	86,3	39	88,6	3,419	10,245
FU MONTH 24	Other	49	94,2	45	91,8	2,222	8,409	43	84,3	39	90,7	1,709	7,449
FU MONTH 36	Other	49	94,2	44	89,8	2,273	8,499	39	76,5	33	84,6	5,051	12,137
BASELINE	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	13,333	18,257	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	5	100,0	5	100,0	20,000	29,814	2	100,0	2	100,0	16,667	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	26,667	43,461	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	25,000	50,000	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC08_SG.xls
11AUG2020 16:18

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Financial Difficulties Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1750	96,6	21,581	29,171	1823	100,0	1773	97,3	22,598	29,914
END OF ANTHRACYCLINE	n/a	1432	79,1	1338	93,4	22,272	29,295	1446	79,3	1356	93,8	22,984	29,955
WEEK 13	n/a	1688	93,2	1599	94,7	24,349	30,534	1725	94,6	1635	94,8	24,241	29,827
WEEK 25	n/a	1645	90,8	1574	95,7	23,189	29,777	1688	92,6	1599	94,7	22,055	29,053
END OF TREATMENT	n/a	1794	99,1	1568	87,4	19,579	28,030	1811	99,3	1621	89,5	19,761	28,149
FU MONTH 18	n/a	1663	91,8	1479	88,9	17,422	26,906	1688	92,6	1470	87,1	17,483	26,955
FU MONTH 24	n/a	1633	90,2	1432	87,7	15,782	25,826	1638	89,9	1424	86,9	15,449	26,005
FU MONTH 36	n/a	1571	86,7	1390	88,5	13,645	24,000	1556	85,4	1349	86,7	13,986	25,397
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	10,204	23,770	43	100,0	40	93,0	15,000	27,164
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	9,677	17,625	26	60,5	25	96,2	22,667	30,000
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	14,394	25,312	40	93,0	39	97,5	16,239	28,482
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	16,279	26,599	38	88,4	35	92,1	16,190	30,648
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	13,636	23,092	42	97,7	37	88,1	7,207	20,987
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	8,527	17,955	39	90,7	36	92,3	10,185	26,210

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	7,752	19,020	39	90,7	34	87,2	7,843	21,802
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	7,407	15,713	39	90,7	37	94,9	4,505	11,553
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	247	96,1	17,274	26,855	278	100,0	271	97,5	18,819	27,414
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	17,603	26,321	203	73,0	190	93,6	22,105	30,327
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	20,000	27,598	263	94,6	253	96,2	23,188	29,663
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	19,550	27,743	256	92,1	246	96,1	22,087	29,585
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	15,272	26,268	276	99,3	255	92,4	19,608	28,506
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	217	88,2	13,518	24,461	259	93,2	232	89,6	17,098	26,131
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	10,686	21,622	256	92,1	229	89,5	14,556	25,776
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	9,767	20,951	251	90,3	227	90,4	13,363	26,096
BASELINE	1-3 positive nodes	907	100,0	882	97,2	20,937	28,895	900	100,0	874	97,1	22,693	30,102
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	658	92,3	22,036	29,696	707	78,6	663	93,8	22,272	29,741
WEEK 13	1-3 positive nodes	847	93,4	799	94,3	24,406	30,559	854	94,9	805	94,3	23,727	29,813
WEEK 25	1-3 positive nodes	825	91,0	782	94,8	22,379	29,520	836	92,9	790	94,5	20,675	28,034
END OF TREATMENT	1-3 positive nodes	899	99,1	779	86,7	19,213	27,466	897	99,7	806	89,9	19,148	27,226
FU MONTH 18	1-3 positive nodes	838	92,4	735	87,7	16,916	26,207	852	94,7	741	87,0	16,689	26,145

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	15,727	25,748	830	92,2	726	87,5	15,289	25,738
FU MONTH 36	1-3 positive nodes	804	88,6	703	87,4	13,561	24,188	794	88,2	666	83,9	13,213	24,229
BASELINE	>= 4 positive nodes	596	100,0	572	96,0	25,408	30,424	602	100,0	588	97,7	24,717	30,724
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	471	95,0	25,195	30,009	510	84,7	478	93,7	24,338	30,148
WEEK 13	>= 4 positive nodes	547	91,8	521	95,2	27,063	31,810	568	94,4	538	94,7	26,084	29,951
WEEK 25	>= 4 positive nodes	533	89,4	512	96,1	26,693	30,990	558	92,7	528	94,6	24,495	30,071
END OF TREATMENT	>= 4 positive nodes	590	99,0	518	87,8	22,523	29,667	596	99,0	523	87,8	21,670	29,577
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	20,730	29,167	538	89,4	461	85,7	19,523	28,567
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	18,985	27,741	513	85,2	435	84,8	16,782	26,810
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	16,393	25,470	472	78,4	419	88,8	16,388	27,414
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1395	96,9	20,597	28,336	1448	100,0	1408	97,2	21,354	29,368
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1336	93,5	22,305	29,304	1444	99,7	1355	93,8	22,952	29,943
WEEK 13	Anthracycline containing regimen	1347	93,6	1287	95,5	23,724	30,264	1374	94,9	1302	94,8	22,401	28,885
WEEK 25	Anthracycline containing regimen	1311	91,1	1249	95,3	22,712	29,526	1346	93,0	1274	94,7	20,042	27,956
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1254	87,8	19,086	27,917	1444	99,7	1296	89,8	18,261	27,275

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1180	88,8	16,751	26,745	1340	92,5	1174	87,6	16,070	26,244
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	15,387	25,590	1308	90,3	1135	86,8	14,802	25,587
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1109	88,1	13,285	23,353	1244	85,9	1083	87,1	12,989	24,730
BASELINE	Non-anthracycline containing regimen	372	100,0	355	95,4	25,446	31,994	375	100,0	365	97,3	27,397	31,518
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	0,000	0,000	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	312	91,5	26,923	31,541	351	93,6	333	94,9	31,431	32,309
WEEK 25	Non-anthracycline containing regimen	334	89,8	325	97,3	25,026	30,699	342	91,2	325	95,0	29,949	31,842
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	314	86,0	21,550	28,435	367	97,9	325	88,6	25,744	30,718
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	20,067	27,419	348	92,8	296	85,1	23,086	28,983
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	17,366	26,738	330	88,0	289	87,6	17,993	27,484
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	15,065	26,398	312	83,2	266	85,3	18,045	27,628
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	835	96,6	20,439	29,018	858	100,0	839	97,8	22,169	29,602
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	636	94,6	22,222	29,261	661	77,0	617	93,3	25,068	31,527
WEEK 13	Negative (ER and PgR negative)	815	94,3	773	94,8	23,286	29,746	804	93,7	770	95,8	24,372	29,915
WEEK 25	Negative (ER and PgR negative)	799	92,5	769	96,2	22,497	28,533	786	91,6	750	95,4	22,400	29,366
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	762	89,0	18,066	26,834	854	99,5	763	89,3	18,698	27,481
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	714	89,1	16,387	26,080	781	91,0	693	88,7	17,268	26,911
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	14,169	23,540	763	88,9	675	88,5	15,259	25,406
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	12,161	22,090	735	85,7	654	89,0	14,118	25,617
BASELINE	Positive (ER and/or PgR positive)	947	100,0	915	96,6	22,623	29,286	965	100,0	934	96,8	22,984	30,202
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	702	92,4	22,317	29,346	785	81,3	739	94,1	21,245	28,482
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	826	94,6	25,343	31,238	921	95,4	865	93,9	24,123	29,766
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	805	95,2	23,851	30,921	902	93,5	849	94,1	21,751	28,788
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	806	85,9	21,009	29,060	957	99,2	858	89,7	20,707	28,713
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	765	88,7	18,388	27,637	907	94,0	777	85,7	17,675	27,011
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	17,299	27,735	875	90,7	749	85,6	15,621	26,549

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	713	87,2	15,054	25,619	821	85,1	695	84,7	13,861	25,206
Geographical region II													
BASELINE	USA/Canada	265	100,0	256	96,6	25,000	32,067	260	100,0	254	97,7	29,528	33,247
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	22,222	28,274	111	42,7	105	94,6	31,429	33,914
WEEK 13	USA/Canada	242	91,3	225	93,0	29,333	31,478	236	90,8	224	94,9	32,589	34,210
WEEK 25	USA/Canada	234	88,3	223	95,3	25,710	30,126	230	88,5	219	95,2	29,680	32,667
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	20,679	28,291	255	98,1	229	89,8	25,036	32,355
FU MONTH 18	USA/Canada	238	89,8	192	80,7	21,875	28,874	231	88,8	179	77,5	23,464	31,336
FU MONTH 24	USA/Canada	231	87,2	188	81,4	18,085	27,863	224	86,2	177	79,0	17,326	28,668
FU MONTH 36	USA/Canada	223	84,2	180	80,7	14,259	23,905	205	78,8	156	76,1	14,316	26,535
BASELINE	Western Europe	827	100,0	781	94,4	16,987	27,662	822	100,0	783	95,3	15,453	26,991
END OF ANTHRACYCLINE	Western Europe	732	88,5	661	90,3	19,213	28,821	728	88,6	658	90,4	18,946	28,887
WEEK 13	Western Europe	764	92,4	696	91,1	21,456	30,546	778	94,6	707	90,9	19,283	28,673
WEEK 25	Western Europe	738	89,2	687	93,1	20,912	30,347	750	91,2	678	90,4	17,207	27,276
END OF TREATMENT	Western Europe	821	99,3	688	83,8	18,508	29,931	817	99,4	698	85,4	16,141	27,148
FU MONTH 18	Western Europe	754	91,2	647	85,8	15,920	27,617	764	92,9	629	82,3	13,778	25,466
FU MONTH 24	Western Europe	739	89,4	613	82,9	14,301	26,547	747	90,9	618	82,7	12,190	24,280
FU MONTH 36	Western Europe	713	86,2	612	85,8	12,364	25,113	712	86,6	594	83,4	11,111	23,788
BASELINE	Asia Pacific	490	100,0	486	99,2	25,789	29,703	512	100,0	508	99,2	28,084	30,605
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	373	97,9	26,184	30,372	397	77,5	390	98,2	25,812	30,240
WEEK 13	Asia Pacific	466	95,1	465	99,8	24,301	28,695	493	96,3	492	99,8	26,355	29,148
WEEK 25	Asia Pacific	461	94,1	460	99,8	24,203	28,751	492	96,1	488	99,2	23,839	28,715

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	19,899	25,248	512	100,0	489	95,5	20,723	26,696
FU MONTH 18	Asia Pacific	459	93,7	450	98,0	16,815	24,798	485	94,7	470	96,9	19,149	26,610
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	16,553	23,797	470	91,8	448	95,3	17,187	25,220
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	15,108	22,488	453	88,5	432	95,4	16,744	26,577
BASELINE	Latin America	43	100,0	43	100,0	17,829	23,400	47	100,0	46	97,9	34,058	29,388
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	25,287	27,682	32	68,1	32	100,0	25,000	29,329
WEEK 13	Latin America	40	93,0	40	100,0	25,000	26,954	44	93,6	43	97,7	27,907	27,149
WEEK 25	Latin America	39	90,7	39	100,0	20,513	26,063	44	93,6	44	100,0	27,273	28,999
END OF TREATMENT	Latin America	42	97,7	38	90,5	17,544	24,183	45	95,7	42	93,3	26,190	28,069
FU MONTH 18	Latin America	41	95,3	37	90,2	19,820	26,597	42	89,4	40	95,2	24,167	28,231
FU MONTH 24	Latin America	40	93,0	36	90,0	13,889	24,398	41	87,2	39	95,1	23,932	28,561
FU MONTH 36	Latin America	38	88,4	34	89,5	10,784	19,627	37	78,7	36	97,3	17,593	20,293
BASELINE	Other	186	100,0	184	98,9	26,087	28,235	182	100,0	182	100,0	25,458	28,556
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	25,048	28,565	178	97,8	171	96,1	26,511	28,906
WEEK 13	Other	176	94,6	173	98,3	29,480	33,496	174	95,6	169	97,1	26,824	27,525
WEEK 25	Other	173	93,0	165	95,4	27,071	30,038	172	94,5	170	98,8	25,098	28,967
END OF TREATMENT	Other	185	99,5	162	87,6	22,222	27,802	182	100,0	163	89,6	23,313	28,481
FU MONTH 18	Other	171	91,9	153	89,5	19,390	26,932	166	91,2	152	91,6	18,860	26,208
FU MONTH 24	Other	169	90,9	154	91,1	17,100	26,193	156	85,7	142	91,0	19,484	29,773
FU MONTH 36	Other	160	86,0	147	91,9	14,739	24,404	149	81,9	131	87,9	16,539	27,229
Protocol version													
BASELINE	Protocol A	1240	100,0	1198	96,6	20,284	28,636	1246	100,0	1208	97,0	21,358	29,229

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	912	92,7	20,175	28,370	988	79,3	924	93,5	22,367	29,522
WEEK 13	Protocol A	1155	93,1	1105	95,7	22,655	29,498	1180	94,7	1111	94,2	23,462	29,503
WEEK 25	Protocol A	1125	90,7	1078	95,8	21,058	28,743	1157	92,9	1090	94,2	21,162	28,724
END OF TREATMENT	Protocol A	1229	99,1	1072	87,2	17,693	27,463	1236	99,2	1109	89,7	18,575	27,234
FU MONTH 18	Protocol A	1142	92,1	1022	89,5	15,819	26,201	1156	92,8	1001	86,6	16,017	26,031
FU MONTH 24	Protocol A	1124	90,6	994	88,4	14,520	25,263	1127	90,4	979	86,9	14,334	25,132
FU MONTH 36	Protocol A	1087	87,7	979	90,1	12,360	23,265	1069	85,8	933	87,3	13,040	24,663
BASELINE	Protocol Amendment B	571	100,0	552	96,7	24,396	30,134	577	100,0	565	97,9	25,251	31,189
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	426	95,1	26,761	30,740	458	79,4	432	94,3	24,306	30,856
WEEK 13	Protocol Amendment B	533	93,3	494	92,7	28,138	32,442	545	94,5	524	96,1	25,891	30,465
WEEK 25	Protocol Amendment B	520	91,1	496	95,4	27,823	31,443	531	92,0	509	95,9	23,969	29,683
END OF TREATMENT	Protocol Amendment B	565	98,9	496	87,8	23,656	28,826	575	99,7	512	89,0	22,331	29,902
FU MONTH 18	Protocol Amendment B	521	91,2	457	87,7	21,007	28,119	532	92,2	469	88,2	20,611	28,607
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	18,645	26,870	511	88,6	445	87,1	17,903	27,701
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	16,707	25,437	487	84,4	416	85,4	16,106	26,881
Nodal status													
BASELINE	0 positive nodes	308	100,0	296	96,1	16,104	26,462	321	100,0	311	96,9	18,328	27,368
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	16,427	25,344	229	71,3	215	93,9	22,171	30,220
WEEK 13	0 positive nodes	294	95,5	279	94,9	19,116	27,283	303	94,4	292	96,4	22,260	29,556
WEEK 25	0 positive nodes	287	93,2	280	97,6	19,048	27,549	294	91,6	281	95,6	21,352	29,727
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	15,006	25,746	318	99,1	292	91,8	18,037	27,944
FU MONTH 18	0 positive nodes	292	94,8	260	89,0	12,692	23,552	298	92,8	268	89,9	16,169	26,199

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	10,185	21,194	295	91,9	263	89,2	13,688	25,360
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	9,359	20,135	290	90,3	264	91,0	12,121	24,758
BASELINE	>= 1 positive nodes	1503	100,0	1454	96,7	22,696	29,576	1502	100,0	1462	97,3	23,507	30,359
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1129	93,4	23,354	29,854	1217	81,0	1141	93,8	23,138	29,916
WEEK 13	>= 1 positive nodes	1394	92,7	1320	94,7	25,455	31,074	1422	94,7	1343	94,4	24,671	29,880
WEEK 25	>= 1 positive nodes	1358	90,4	1294	95,3	24,086	30,172	1394	92,8	1318	94,5	22,205	28,917
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1297	87,1	20,535	28,400	1493	99,4	1329	89,0	20,140	28,190
FU MONTH 18	>= 1 positive nodes	1371	91,2	1219	88,9	18,430	27,472	1390	92,5	1202	86,5	17,776	27,123
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	16,977	26,566	1343	89,4	1161	86,4	15,848	26,143
FU MONTH 36	>= 1 positive nodes	1288	85,7	1130	87,7	14,631	24,707	1266	84,3	1085	85,7	14,439	25,541
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	851	97,5	23,737	30,346	885	100,0	866	97,9	25,481	30,830
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	23,605	30,262	726	82,0	692	95,3	25,530	31,063
WEEK 13	Premenopausal	841	96,3	804	95,6	26,036	31,288	852	96,3	808	94,8	26,444	29,927
WEEK 25	Premenopausal	825	94,5	794	96,2	24,265	30,713	838	94,7	799	95,3	23,279	28,911
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	21,319	28,776	881	99,5	807	91,6	21,066	29,228
FU MONTH 18	Premenopausal	819	93,8	723	88,3	19,272	28,134	835	94,4	736	88,1	19,611	28,152
FU MONTH 24	Premenopausal	803	92,0	704	87,7	16,951	26,845	807	91,2	707	87,6	16,030	26,627

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	15,278	25,699	773	87,3	667	86,3	14,993	25,738
BASELINE	Postmenopausal	933	100,0	894	95,8	19,612	27,920	929	100,0	899	96,8	19,911	28,797
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	658	91,5	21,023	28,291	711	76,5	658	92,5	20,314	28,628
WEEK 13	Postmenopausal	842	90,2	791	93,9	22,714	29,713	864	93,0	819	94,8	21,978	29,575
WEEK 25	Postmenopausal	815	87,4	775	95,1	22,194	28,816	841	90,5	793	94,3	20,891	29,242
END OF TREATMENT	Postmenopausal	923	98,9	801	86,8	17,936	27,261	921	99,1	806	87,5	18,486	27,024
FU MONTH 18	Postmenopausal	839	89,9	753	89,7	15,671	25,601	844	90,9	726	86,0	15,335	25,562
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	14,641	24,804	823	88,6	712	86,5	14,841	25,247
FU MONTH 36	Postmenopausal	801	85,9	714	89,1	12,185	22,247	776	83,5	676	87,1	13,018	25,040
BASELINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	8	88,9	12,500	24,801
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	6	66,7	22,222	17,213
WEEK 13	Unknown/Missing	5	100,0	4	80,0	8,333	16,667	9	100,0	8	88,9	33,333	30,861
WEEK 25	Unknown/Missing	5	100,0	5	100,0	6,667	14,907	9	100,0	7	77,8	14,286	17,817
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	9	100,0	8	88,9	16,667	25,198
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	11,111	19,245	9	100,0	8	88,9	16,667	25,198
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	16,667	19,245	8	88,9	5	62,5	20,000	44,721
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	0,000	0,000	7	77,8	6	85,7	11,111	27,217
Age II													
BASELINE	< 65	1581	100,0	1533	97,0	22,657	29,670	1604	100,0	1566	97,6	23,734	30,276
END OF ANTHRACYCLINE	< 65	1268	80,2	1193	94,1	23,247	29,785	1287	80,2	1218	94,6	24,138	30,386
WEEK 13	< 65	1497	94,7	1423	95,1	25,322	30,999	1529	95,3	1453	95,0	25,510	30,265

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1398	95,5	24,058	30,148	1501	93,6	1426	95,0	22,955	29,310
END OF TREATMENT	< 65	1569	99,2	1381	88,0	20,444	28,340	1596	99,5	1440	90,2	20,463	28,383
FU MONTH 18	< 65	1474	93,2	1308	88,7	18,323	27,410	1497	93,3	1315	87,8	18,124	27,344
FU MONTH 24	< 65	1446	91,5	1262	87,3	16,508	26,308	1450	90,4	1268	87,4	15,799	26,357
FU MONTH 36	< 65	1390	87,9	1233	88,7	14,436	24,632	1383	86,2	1201	86,8	14,627	26,030
BASELINE	>= 65	230	100,0	217	94,3	13,978	24,092	219	100,0	207	94,5	14,010	25,487
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	14,253	23,487	159	72,6	138	86,8	12,802	23,595
WEEK 13	>= 65	191	83,0	176	92,1	16,477	25,197	196	89,5	182	92,9	14,103	23,819
WEEK 25	>= 65	181	78,7	176	97,2	16,288	25,694	187	85,4	173	92,5	14,644	25,746
END OF TREATMENT	>= 65	225	97,8	187	83,1	13,191	24,771	215	98,2	181	84,2	14,180	25,609
FU MONTH 18	>= 65	189	82,2	171	90,5	10,526	21,534	191	87,2	155	81,2	12,043	22,755
FU MONTH 24	>= 65	187	81,3	170	90,9	10,392	21,218	188	85,8	156	83,0	12,607	22,826
FU MONTH 36	>= 65	181	78,7	157	86,7	7,431	17,130	173	79,0	148	85,5	8,784	18,793
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	21,505	27,953	24	100,0	24	100,0	33,333	35,441
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	13,725	23,743	17	70,8	16	94,1	29,167	40,139
WEEK 13	Grade 1	31	96,9	30	96,8	32,222	36,602	23	95,8	22	95,7	33,333	29,096
WEEK 25	Grade 1	31	96,9	28	90,3	30,952	37,327	23	95,8	22	95,7	31,818	29,951
END OF TREATMENT	Grade 1	31	96,9	27	87,1	20,988	33,523	24	100,0	22	91,7	21,212	21,932
FU MONTH 18	Grade 1	30	93,8	27	90,0	19,753	32,370	23	95,8	22	95,7	27,273	24,422
FU MONTH 24	Grade 1	28	87,5	27	96,4	22,222	35,806	23	95,8	21	91,3	20,635	26,825
FU MONTH 36	Grade 1	27	84,4	26	96,3	20,513	34,094	22	91,7	20	90,9	21,667	29,170
BASELINE	Grade 2	552	100,0	534	96,7	22,035	29,151	557	100,0	542	97,3	24,354	30,625
END OF ANTHRACYCLINE	Grade 2	445	80,6	422	94,8	23,460	30,737	446	80,1	422	94,6	23,223	29,024

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	24,536	30,235	524	94,1	504	96,2	24,405	29,005
WEEK 25	Grade 2	494	89,5	477	96,6	23,550	30,362	515	92,5	492	95,5	24,051	29,125
END OF TREATMENT	Grade 2	548	99,3	485	88,5	19,931	28,126	553	99,3	493	89,2	21,095	28,456
FU MONTH 18	Grade 2	507	91,8	455	89,7	16,117	25,207	517	92,8	447	86,5	18,941	27,865
FU MONTH 24	Grade 2	501	90,8	449	89,6	15,516	25,282	500	89,8	431	86,2	16,319	26,980
FU MONTH 36	Grade 2	487	88,2	437	89,7	12,967	22,793	476	85,5	414	87,0	16,103	27,514
BASELINE	Grade 3	1161	100,0	1123	96,7	21,342	29,397	1173	100,0	1139	97,1	21,744	29,484
END OF ANTHRACYCLINE	Grade 3	918	79,1	851	92,7	21,974	28,724	919	78,3	856	93,1	23,287	30,295
WEEK 13	Grade 3	1088	93,7	1024	94,1	24,186	30,596	1114	95,0	1049	94,2	24,309	30,180
WEEK 25	Grade 3	1059	91,2	1011	95,5	23,145	29,341	1087	92,7	1023	94,1	21,277	29,199
END OF TREATMENT	Grade 3	1150	99,1	995	86,5	19,531	27,921	1165	99,3	1046	89,8	19,184	28,155
FU MONTH 18	Grade 3	1067	91,9	944	88,5	17,973	27,300	1085	92,5	943	86,9	16,684	26,509
FU MONTH 24	Grade 3	1046	90,1	902	86,2	15,669	25,678	1053	89,8	916	87,0	15,066	25,533
FU MONTH 36	Grade 3	1002	86,3	875	87,3	13,638	23,959	999	85,2	864	86,5	12,886	24,200
BASELINE	Unevaluable/Unknown/Missing	66	100,0	62	93,9	22,043	26,270	69	100,0	68	98,6	19,118	28,399
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	20,139	28,133	64	92,8	62	96,9	15,591	28,128
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	60	96,8	21,667	28,671	64	92,8	60	93,8	18,333	30,331
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	17,241	28,092	63	91,3	62	98,4	15,591	23,929
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	16,940	26,959	69	100,0	60	87,0	18,333	27,736
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	53	89,8	17,610	31,080	63	91,3	58	92,1	15,517	27,370

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	16,667	27,281	62	89,9	56	90,3	13,095	25,959
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	16,026	28,385	59	85,5	51	86,4	12,418	24,909
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	702	96,4	17,189	27,506	715	100,0	686	95,9	17,153	27,237
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	543	91,7	18,662	28,341	572	80,0	520	90,9	18,590	27,772
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	21,141	29,784	673	94,1	632	93,9	19,989	28,266
WEEK 25	Breast conserving surgery	665	91,3	635	95,5	19,633	28,323	654	91,5	614	93,9	19,055	28,188
END OF TREATMENT	Breast conserving surgery	722	99,2	621	86,0	17,230	28,051	711	99,4	619	87,1	16,909	27,503
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	13,772	24,190	659	92,2	557	84,5	14,662	25,806
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	12,674	23,905	644	90,1	554	86,0	11,793	23,577
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	9,549	20,630	616	86,2	535	86,9	11,464	23,380
BASELINE	Mastectomy	1083	100,0	1048	96,8	24,523	29,889	1107	100,0	1086	98,1	26,059	31,014
END OF ANTHRACYCLINE	Mastectomy	840	77,6	795	94,6	24,738	29,695	873	78,9	835	95,6	25,749	30,945
WEEK 13	Mastectomy	1011	93,4	962	95,2	26,473	30,852	1051	94,9	1002	95,3	26,946	30,484
WEEK 25	Mastectomy	980	90,5	939	95,8	25,595	30,501	1033	93,3	984	95,3	23,950	29,445
END OF TREATMENT	Mastectomy	1072	99,0	947	88,3	21,119	27,923	1099	99,3	1001	91,1	21,545	28,418
FU MONTH 18	Mastectomy	985	91,0	886	89,9	19,865	28,332	1028	92,9	912	88,7	19,225	27,513
FU MONTH 24	Mastectomy	967	89,3	856	88,5	17,874	26,853	993	89,7	869	87,5	17,798	27,207

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	828	90,0	16,425	25,683	939	84,8	814	86,7	15,643	26,523
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	638	96,7	18,809	27,731	665	100,0	641	96,4	19,709	28,895
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	479	92,3	19,137	28,324	523	78,6	490	93,7	21,361	29,492
WEEK 13	0 - < 2 cm	620	93,9	582	93,9	21,363	29,269	631	94,9	605	95,9	21,818	28,797
WEEK 25	0 - < 2 cm	608	92,1	579	95,2	20,035	28,239	617	92,8	588	95,3	20,181	28,412
END OF TREATMENT	0 - < 2 cm	655	99,2	575	87,8	17,913	27,368	661	99,4	595	90,0	17,031	26,332
FU MONTH 18	0 - < 2 cm	617	93,5	543	88,0	15,163	24,908	624	93,8	557	89,3	14,183	24,896
FU MONTH 24	0 - < 2 cm	607	92,0	533	87,8	14,321	24,721	606	91,1	530	87,5	12,201	23,681
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	11,810	22,470	580	87,2	506	87,2	11,331	23,711
BASELINE	>= 2 - < 5 cm	1009	100,0	973	96,4	23,090	29,419	991	100,0	967	97,6	23,681	30,085
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	751	94,2	23,657	29,331	789	79,6	740	93,8	23,378	30,110
WEEK 13	>= 2 - < 5 cm	935	92,7	891	95,3	25,215	30,398	940	94,9	888	94,5	25,526	30,472
WEEK 25	>= 2 - < 5 cm	910	90,2	876	96,3	24,696	30,325	919	92,7	864	94,0	22,955	29,266
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	866	86,8	19,861	27,913	985	99,4	874	88,7	21,129	29,089

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	826	89,5	18,079	27,488	914	92,2	781	85,4	19,676	28,165
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	16,815	26,785	889	89,7	776	87,3	17,784	27,647
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	14,348	24,669	839	84,7	726	86,5	15,794	26,580
BASELINE	>= 5 cm	139	100,0	137	98,6	23,844	33,075	165	100,0	163	98,8	27,198	31,912
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	26,349	32,257	132	80,0	124	93,9	26,613	30,645
WEEK 13	>= 5 cm	130	93,5	123	94,6	31,707	35,156	152	92,1	140	92,1	25,952	29,127
WEEK 25	>= 5 cm	124	89,2	116	93,5	27,011	31,366	150	90,9	145	96,7	23,218	28,954
END OF TREATMENT	>= 5 cm	138	99,3	124	89,9	25,000	30,540	163	98,8	150	92,0	22,222	28,291
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	23,364	30,099	148	89,7	130	87,8	17,949	26,626
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	15,916	24,141	141	85,5	116	82,3	13,218	20,562
FU MONTH 36	>= 5 cm	115	82,7	100	87,0	17,667	25,713	135	81,8	115	85,2	13,333	22,856
BASELINE	Missing	3	100,0	2	66,7	16,667	23,570	2	100,0	2	100,0	50,000	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	50,000	23,570
WEEK 13	Missing	3	100,0	3	100,0	44,444	50,918	2	100,0	2	100,0	66,667	47,140
WEEK 25	Missing	3	100,0	3	100,0	44,444	50,918	2	100,0	2	100,0	100,000	0,000
END OF TREATMENT	Missing	3	100,0	3	100,0	33,333	57,735	2	100,0	2	100,0	50,000	70,711
FU MONTH 18	Missing	3	100,0	3	100,0	33,333	57,735	2	100,0	2	100,0	50,000	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	0,000	0,000	2	100,0	2	100,0	100,000	0,000
FU MONTH 36	Missing	3	100,0	3	100,0	22,222	38,490	2	100,0	2	100,0	66,667	47,140
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1312	97,4	21,087	29,329	1350	100,0	1311	97,1	21,053	29,081
END OF ANTHRACYCLINE	Yes	1103	81,9	1043	94,6	22,148	29,363	1104	81,8	1037	93,9	21,311	28,795
WEEK 13	Yes	1308	97,1	1239	94,7	24,617	31,210	1324	98,1	1248	94,3	22,756	28,977
WEEK 25	Yes	1277	94,8	1218	95,4	23,125	29,771	1302	96,4	1227	94,2	21,163	28,851

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1208	89,7	19,592	28,279	1350	100,0	1230	91,1	18,753	27,765
FU MONTH 18	Yes	1291	95,8	1142	88,5	17,426	27,399	1298	96,1	1128	86,9	16,608	26,345
FU MONTH 24	Yes	1266	94,0	1109	87,6	15,750	26,198	1260	93,3	1089	86,4	14,080	25,035
FU MONTH 36	Yes	1219	90,5	1061	87,0	13,258	23,662	1195	88,5	1034	86,5	12,863	24,609
BASELINE	No	464	100,0	438	94,4	23,059	28,675	473	100,0	462	97,7	26,984	31,788
END OF ANTHRACYCLINE	No	329	70,9	295	89,7	22,712	29,099	342	72,3	319	93,3	28,422	32,915
WEEK 13	No	380	81,9	360	94,7	23,426	28,104	401	84,8	387	96,5	29,027	31,991
WEEK 25	No	368	79,3	356	96,7	23,408	29,837	386	81,6	372	96,4	25,000	29,560
END OF TREATMENT	No	447	96,3	360	80,5	19,537	27,216	461	97,5	391	84,8	22,933	29,134
FU MONTH 18	No	372	80,2	337	90,6	17,409	25,203	390	82,5	342	87,7	20,370	28,728
FU MONTH 24	No	367	79,1	323	88,0	15,893	24,544	378	79,9	335	88,6	19,900	28,525
FU MONTH 36	No	352	75,9	329	93,5	14,894	25,055	361	76,3	315	87,3	17,672	27,548
Race													
BASELINE	White	1252	100,0	1196	95,5	19,175	28,083	1255	100,0	1212	96,6	19,417	28,298
END OF ANTHRACYCLINE	White	1010	80,7	928	91,9	20,295	28,444	1018	81,1	936	91,9	20,691	29,054
WEEK 13	White	1158	92,5	1078	93,1	23,717	30,863	1183	94,3	1095	92,6	22,588	29,609
WEEK 25	White	1120	89,5	1055	94,2	22,243	29,938	1150	91,6	1069	93,0	20,143	28,589
END OF TREATMENT	White	1238	98,9	1043	84,2	19,207	29,000	1244	99,1	1083	87,1	18,744	28,456
FU MONTH 18	White	1138	90,9	977	85,9	17,059	27,247	1152	91,8	964	83,7	15,768	26,580
FU MONTH 24	White	1115	89,1	942	84,5	15,145	26,384	1120	89,2	939	83,8	13,951	25,813
FU MONTH 36	White	1071	85,5	922	86,1	12,437	24,105	1064	84,8	897	84,3	12,189	24,602
BASELINE	Black	25	100,0	24	96,0	31,944	36,088	31	100,0	30	96,8	52,222	41,692
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	25,926	36,430	15	48,4	14	93,3	64,286	38,038
WEEK 13	Black	21	84,0	17	81,0	39,216	37,704	29	93,5	28	96,6	50,000	37,952

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	18	85,7	37,037	39,422	29	93,5	28	96,6	47,619	35,635
END OF TREATMENT	Black	24	96,0	22	91,7	15,152	26,681	31	100,0	28	90,3	42,857	34,969
FU MONTH 18	Black	23	92,0	17	73,9	23,529	32,839	29	93,5	24	82,8	37,500	38,464
FU MONTH 24	Black	22	88,0	18	81,8	18,519	34,721	28	90,3	23	82,1	24,638	35,129
FU MONTH 36	Black	22	88,0	18	81,8	20,370	28,328	26	83,9	20	76,9	28,333	36,314
BASELINE	Asian	477	100,0	473	99,2	27,132	30,825	484	100,0	480	99,2	28,125	30,812
END OF ANTHRACYCLINE	Asian	370	77,6	359	97,0	26,648	30,593	375	77,5	368	98,1	26,630	30,294
WEEK 13	Asian	455	95,4	450	98,9	24,889	29,309	466	96,3	465	99,8	26,523	29,181
WEEK 25	Asian	450	94,3	448	99,6	24,926	28,921	465	96,1	459	98,7	24,691	28,979
END OF TREATMENT	Asian	475	99,6	452	95,2	20,575	25,637	484	100,0	462	95,5	20,707	26,470
FU MONTH 18	Asian	447	93,7	432	96,6	17,593	25,268	461	95,2	441	95,7	19,803	26,417
FU MONTH 24	Asian	442	92,7	423	95,7	17,021	23,721	445	91,9	421	94,6	17,736	25,240
FU MONTH 36	Asian	424	88,9	401	94,6	15,794	22,483	425	87,8	397	93,4	17,296	26,438
BASELINE	Other	52	100,0	52	100,0	21,154	27,240	51	100,0	50	98,0	29,333	33,428
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	27,027	29,226	36	70,6	36	100,0	29,630	31,651
WEEK 13	Other	49	94,2	49	100,0	27,891	29,928	45	88,2	45	100,0	25,926	28,328
WEEK 25	Other	49	94,2	48	98,0	22,917	30,095	42	82,4	41	97,6	26,016	27,398
END OF TREATMENT	Other	52	100,0	47	90,4	21,277	29,835	50	98,0	47	94,0	20,567	27,411
FU MONTH 18	Other	50	96,2	48	96,0	22,917	32,366	44	86,3	39	88,6	22,222	27,924
FU MONTH 24	Other	49	94,2	45	91,8	17,037	29,833	43	84,3	39	90,7	21,368	30,095
FU MONTH 36	Other	49	94,2	44	89,8	17,424	31,736	39	76,5	33	84,6	15,152	20,566
BASELINE	Missing	5	100,0	5	100,0	26,667	36,515	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	33,333	47,140	2	100,0	2	100,0	16,667	23,570
WEEK 13	Missing	5	100,0	5	100,0	26,667	43,461	2	100,0	2	100,0	0,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	20,000	18,257	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	8,333	16,667	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	0,000	0,000	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	8,333	16,667	2	100,0	2	100,0	16,667	23,570
FU MONTH 36	Missing	5	100,0	5	100,0	6,667	14,907	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC09_SG.xls
11AUG2020 16:19

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Global Health Status
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1756	97,0	72,314	19,943	1823	100,0	1775	97,4	72,277	19,543
END OF ANTHRACYCLINE	n/a	1432	79,1	1342	93,7	65,176	20,104	1446	79,3	1361	94,1	64,291	19,951
WEEK 13	n/a	1688	93,2	1605	95,1	62,321	20,870	1725	94,6	1637	94,9	62,518	20,314
WEEK 25	n/a	1645	90,8	1575	95,7	68,757	19,472	1688	92,6	1600	94,8	69,469	18,996
END OF TREATMENT	n/a	1794	99,1	1570	87,5	71,131	20,443	1811	99,3	1625	89,7	72,272	19,685
FU MONTH 18	n/a	1663	91,8	1481	89,1	74,381	19,447	1688	92,6	1471	87,1	73,323	19,290
FU MONTH 24	n/a	1633	90,2	1431	87,6	75,198	19,879	1638	89,9	1422	86,8	74,607	19,088
FU MONTH 36	n/a	1571	86,7	1390	88,5	76,337	19,461	1556	85,4	1348	86,6	74,363	20,034
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	77,891	21,283	43	100,0	40	93,0	75,833	21,334
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	64,785	22,434	26	60,5	25	96,2	61,667	21,109
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	63,826	19,518	40	93,0	39	97,5	59,402	21,132
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	71,318	17,845	38	88,4	34	89,5	64,461	17,565
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	72,159	16,854	42	97,7	37	88,1	72,748	18,389
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	77,326	14,356	39	90,7	36	92,3	69,676	21,096

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	79,070	17,666	39	90,7	34	87,2	69,608	17,272
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	78,519	17,542	39	90,7	37	94,9	75,225	14,762
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	251	97,7	73,904	19,398	278	100,0	271	97,5	75,246	19,015
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	177	94,7	65,160	19,240	203	73,0	191	94,1	63,743	21,743
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	63,475	21,194	263	94,6	253	96,2	61,989	20,762
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	68,179	20,305	256	92,1	246	96,1	71,172	17,905
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	71,769	21,209	276	99,3	255	92,4	72,190	20,513
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	74,694	20,300	259	93,2	232	89,6	74,533	19,059
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	76,236	20,003	256	92,1	229	89,5	76,092	19,103
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	77,636	18,690	251	90,3	227	90,4	75,330	19,791
BASELINE	1-3 positive nodes	907	100,0	883	97,4	72,395	19,545	900	100,0	876	97,3	71,965	19,512
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	662	92,8	66,176	19,417	707	78,6	666	94,2	64,464	18,974
WEEK 13	1-3 positive nodes	847	93,4	804	94,9	62,355	20,637	854	94,9	805	94,3	63,209	19,940
WEEK 25	1-3 positive nodes	825	91,0	781	94,7	69,633	18,940	836	92,9	790	94,5	68,914	18,917
END OF TREATMENT	1-3 positive nodes	899	99,1	780	86,8	71,496	20,211	897	99,7	810	90,3	72,212	19,065
FU MONTH 18	1-3 positive nodes	838	92,4	735	87,7	75,170	18,676	852	94,7	741	87,0	73,144	18,554

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	75,401	19,729	830	92,2	725	87,3	74,609	18,506
FU MONTH 36	1-3 positive nodes	804	88,6	703	87,4	76,174	19,875	794	88,2	665	83,8	74,198	20,656
BASELINE	>= 4 positive nodes	596	100,0	573	96,1	71,015	20,575	602	100,0	588	97,7	71,131	19,591
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	63,806	21,166	510	84,7	479	93,9	64,405	20,514
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	61,622	21,215	568	94,4	540	95,1	61,960	20,603
WEEK 25	>= 4 positive nodes	533	89,4	514	96,4	67,477	19,967	558	92,7	530	95,0	69,827	19,641
END OF TREATMENT	>= 4 positive nodes	590	99,0	519	88,0	70,215	20,748	596	99,0	523	87,8	72,371	20,350
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	72,784	20,506	538	89,4	462	85,9	73,286	20,403
FU MONTH 24	>= 4 positive nodes	516	86,6	452	87,6	74,023	20,234	513	85,2	434	84,6	74,213	20,124
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	75,722	19,362	472	78,4	419	88,8	74,025	19,604
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1398	97,2	72,192	19,985	1448	100,0	1411	97,4	71,923	19,294
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1340	93,8	65,149	20,107	1444	99,7	1360	94,2	64,289	19,958
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	62,294	20,554	1374	94,9	1303	94,8	62,414	20,077
WEEK 25	Anthracycline containing regimen	1311	91,1	1250	95,3	68,893	19,351	1346	93,0	1275	94,7	69,105	19,278
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1255	87,8	70,637	20,587	1444	99,7	1301	90,1	71,720	19,856

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1182	88,9	74,041	19,427	1340	92,5	1175	87,7	72,922	19,381
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	74,716	20,064	1308	90,3	1133	86,6	73,956	19,421
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1109	88,1	76,292	19,375	1244	85,9	1082	87,0	74,253	20,299
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	72,789	19,802	375	100,0	364	97,1	73,649	20,447
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	83,333	0,000	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	313	91,8	62,433	22,160	351	93,6	334	95,2	62,924	21,237
WEEK 25	Non-anthracycline containing regimen	334	89,8	325	97,3	68,231	19,953	342	91,2	325	95,0	70,897	17,806
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	73,095	19,771	367	97,9	324	88,3	74,486	18,851
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	75,725	19,500	348	92,8	296	85,1	74,916	18,872
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	285	87,2	77,135	19,025	330	88,0	289	87,6	77,163	17,524
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	76,512	19,832	312	83,2	266	85,3	74,812	18,947
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	839	97,1	72,954	20,076	858	100,0	840	97,9	73,274	19,222
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	636	94,6	64,741	20,173	661	77,0	621	93,9	63,298	21,118
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	63,155	20,918	804	93,7	772	96,0	62,111	20,349
WEEK 25	Negative (ER and PgR negative)	799	92,5	769	96,2	69,062	19,263	786	91,6	749	95,3	69,637	19,062
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	71,090	20,542	854	99,5	763	89,3	72,357	19,286
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	716	89,4	74,884	19,317	781	91,0	694	88,9	73,655	19,514
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	75,564	19,839	763	88,9	675	88,5	74,593	18,972
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	76,292	18,975	735	85,7	653	88,8	74,464	19,967
BASELINE	Positive (ER and/or PgR positive)	947	100,0	917	96,8	71,728	19,814	965	100,0	935	96,9	71,381	19,794
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	65,569	20,049	785	81,3	740	94,3	65,124	18,891
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	829	95,0	61,540	20,808	921	95,4	865	93,9	62,881	20,287
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	806	95,3	68,466	19,677	902	93,5	851	94,3	69,320	18,948
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	807	86,0	71,169	20,363	957	99,2	862	90,1	72,196	20,042
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	765	88,7	73,911	19,569	907	94,0	777	85,7	73,027	19,095
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	737	87,1	74,853	19,923	875	90,7	747	85,4	74,621	19,206

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	713	87,2	76,379	19,925	821	85,1	695	84,7	74,269	20,110
Geographical region II													
BASELINE	USA/Canada	265	100,0	256	96,6	75,000	20,346	260	100,0	255	98,1	74,673	20,370
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	68,709	19,069	111	42,7	105	94,6	62,937	20,992
WEEK 13	USA/Canada	242	91,3	228	94,2	63,670	20,446	236	90,8	224	94,9	64,063	21,118
WEEK 25	USA/Canada	234	88,3	224	95,7	71,205	19,295	230	88,5	219	95,2	72,336	19,662
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	75,772	19,656	255	98,1	228	89,4	75,512	20,043
FU MONTH 18	USA/Canada	238	89,8	194	81,5	77,320	19,016	231	88,8	179	77,5	76,629	20,395
FU MONTH 24	USA/Canada	231	87,2	188	81,4	78,856	18,711	224	86,2	177	79,0	79,237	17,613
FU MONTH 36	USA/Canada	223	84,2	179	80,3	79,423	18,765	205	78,8	156	76,1	78,526	19,902
BASELINE	Western Europe	827	100,0	787	95,2	71,485	20,045	822	100,0	786	95,6	72,699	19,759
END OF ANTHRACYCLINE	Western Europe	732	88,5	664	90,7	65,161	19,316	728	88,6	662	90,9	64,741	19,704
WEEK 13	Western Europe	764	92,4	699	91,5	61,755	20,609	778	94,6	708	91,0	62,382	20,016
WEEK 25	Western Europe	738	89,2	688	93,2	68,411	18,385	750	91,2	679	90,5	69,416	18,167
END OF TREATMENT	Western Europe	821	99,3	690	84,0	69,553	21,011	817	99,4	702	85,9	71,771	20,071
FU MONTH 18	Western Europe	754	91,2	646	85,7	73,181	19,446	764	92,9	629	82,3	73,172	18,316
FU MONTH 24	Western Europe	739	89,4	612	82,8	74,074	20,201	747	90,9	617	82,6	74,352	19,300
FU MONTH 36	Western Europe	713	86,2	612	85,8	75,654	19,951	712	86,6	593	83,3	74,466	19,632
BASELINE	Asia Pacific	490	100,0	487	99,4	72,930	19,499	512	100,0	506	98,8	71,937	19,052
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	64,773	21,633	397	77,5	390	98,2	64,829	20,721
WEEK 13	Asia Pacific	466	95,1	465	99,8	61,774	21,887	493	96,3	492	99,8	61,501	21,047
WEEK 25	Asia Pacific	461	94,1	460	99,8	68,931	20,711	492	96,1	488	99,2	69,348	19,492

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	71,282	20,052	512	100,0	490	95,7	72,092	19,279
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	75,092	19,724	485	94,7	471	97,1	72,912	20,034
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	75,283	19,905	470	91,8	447	95,1	73,527	19,287
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	75,159	19,114	453	88,5	432	95,4	73,418	20,272
BASELINE	Latin America	43	100,0	43	100,0	81,977	15,315	47	100,0	46	97,9	76,449	13,415
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	73,563	17,827	32	68,1	32	100,0	70,833	20,522
WEEK 13	Latin America	40	93,0	40	100,0	65,417	23,536	44	93,6	44	100,0	68,371	17,934
WEEK 25	Latin America	39	90,7	39	100,0	75,427	19,113	44	93,6	44	100,0	73,864	14,555
END OF TREATMENT	Latin America	42	97,7	38	90,5	79,386	20,110	45	95,7	42	93,3	75,397	20,738
FU MONTH 18	Latin America	41	95,3	37	90,2	80,180	19,380	42	89,4	40	95,2	78,750	16,228
FU MONTH 24	Latin America	40	93,0	36	90,0	86,806	11,158	41	87,2	39	95,1	80,769	14,453
FU MONTH 36	Latin America	38	88,4	34	89,5	86,029	14,466	37	78,7	36	97,3	77,778	15,811
BASELINE	Other	186	100,0	183	98,4	68,215	19,937	182	100,0	182	100,0	66,987	19,199
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	62,620	20,166	178	97,8	172	96,6	60,950	17,946
WEEK 13	Other	176	94,6	173	98,3	63,584	18,981	174	95,6	169	97,1	62,475	18,659
WEEK 25	Other	173	93,0	164	94,8	64,787	19,976	172	94,5	170	98,8	65,196	20,217
END OF TREATMENT	Other	185	99,5	162	87,6	69,290	18,955	182	100,0	163	89,6	69,632	17,947
FU MONTH 18	Other	171	91,9	153	89,5	72,222	18,609	166	91,2	152	91,6	69,901	19,656
FU MONTH 24	Other	169	90,9	154	91,1	72,240	20,145	156	85,7	142	91,0	71,655	19,349
FU MONTH 36	Other	160	86,0	147	91,9	76,531	19,434	149	81,9	131	87,9	71,120	21,541
Protocol version													
BASELINE	Protocol A	1240	100,0	1202	96,9	72,338	20,141	1246	100,0	1208	97,0	72,544	19,450

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	914	92,9	66,074	19,923	988	79,3	927	93,8	64,087	20,236
WEEK 13	Protocol A	1155	93,1	1107	95,8	62,918	21,256	1180	94,7	1112	94,2	62,717	20,670
WEEK 25	Protocol A	1125	90,7	1078	95,8	69,728	19,316	1157	92,9	1091	94,3	69,699	19,101
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	71,932	20,297	1236	99,2	1114	90,1	72,397	19,632
FU MONTH 18	Protocol A	1142	92,1	1023	89,6	74,910	19,932	1156	92,8	1002	86,7	73,769	18,669
FU MONTH 24	Protocol A	1124	90,6	993	88,3	75,604	19,652	1127	90,4	978	86,8	74,727	19,473
FU MONTH 36	Protocol A	1087	87,7	979	90,1	76,966	19,320	1069	85,8	932	87,2	74,329	20,223
BASELINE	Protocol Amendment B	571	100,0	554	97,0	72,262	19,526	577	100,0	567	98,3	71,708	19,745
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	63,259	20,378	458	79,4	434	94,8	64,727	19,345
WEEK 13	Protocol Amendment B	533	93,3	498	93,4	60,994	19,942	545	94,5	525	96,3	62,095	19,550
WEEK 25	Protocol Amendment B	520	91,1	497	95,6	66,650	19,661	531	92,0	509	95,9	68,975	18,780
END OF TREATMENT	Protocol Amendment B	565	98,9	497	88,0	69,400	20,670	575	99,7	511	88,9	71,999	19,816
FU MONTH 18	Protocol Amendment B	521	91,2	458	87,9	73,199	18,282	532	92,2	469	88,2	72,370	20,540
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	74,277	20,376	511	88,6	444	86,9	74,343	18,231
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	74,838	19,737	487	84,4	416	85,4	74,439	19,627
Nodal status													
BASELINE	0 positive nodes	308	100,0	300	97,4	74,556	19,736	321	100,0	311	96,9	75,322	19,293
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	208	93,3	65,104	19,690	229	71,3	216	94,3	63,503	21,633
WEEK 13	0 positive nodes	294	95,5	279	94,9	63,530	20,905	303	94,4	292	96,4	61,644	20,794
WEEK 25	0 positive nodes	287	93,2	280	97,6	68,661	19,950	294	91,6	280	95,2	70,357	17,968
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	71,833	20,537	318	99,1	292	91,8	72,260	20,227
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	75,128	19,447	298	92,8	268	89,9	73,881	19,374

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	76,720	19,619	295	91,9	263	89,2	75,253	18,971
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	77,788	18,467	290	90,3	264	91,0	75,316	19,142
BASELINE	>= 1 positive nodes	1503	100,0	1456	96,9	71,852	19,961	1502	100,0	1464	97,5	71,630	19,541
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1134	93,8	65,190	20,188	1217	81,0	1145	94,1	64,440	19,624
WEEK 13	>= 1 positive nodes	1394	92,7	1326	95,1	62,066	20,862	1422	94,7	1345	94,6	62,708	20,211
WEEK 25	>= 1 positive nodes	1358	90,4	1295	95,4	68,777	19,375	1394	92,8	1320	94,7	69,280	19,209
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1299	87,2	70,984	20,429	1493	99,4	1333	89,3	72,274	19,572
FU MONTH 18	>= 1 positive nodes	1371	91,2	1220	89,0	74,221	19,451	1390	92,5	1203	86,5	73,199	19,277
FU MONTH 24	>= 1 positive nodes	1343	89,4	1179	87,8	74,873	19,927	1343	89,4	1159	86,3	74,461	19,120
FU MONTH 36	>= 1 positive nodes	1288	85,7	1130	87,7	76,003	19,675	1266	84,3	1084	85,6	74,131	20,247
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	850	97,4	73,265	19,113	885	100,0	868	98,1	73,531	18,232
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	67,086	18,987	726	82,0	693	95,5	66,643	19,060
WEEK 13	Premenopausal	841	96,3	804	95,6	62,707	19,933	852	96,3	809	95,0	64,349	19,500
WEEK 25	Premenopausal	825	94,5	793	96,1	68,979	19,343	838	94,7	799	95,3	70,046	18,429
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	72,805	19,856	881	99,5	810	91,9	73,981	19,281
FU MONTH 18	Premenopausal	819	93,8	724	88,4	75,794	18,638	835	94,4	737	88,3	74,593	18,441
FU MONTH 24	Premenopausal	803	92,0	704	87,7	77,249	18,521	807	91,2	705	87,4	75,733	18,396

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	77,790	19,301	773	87,3	666	86,2	76,351	18,660
BASELINE	Postmenopausal	933	100,0	901	96,6	71,374	20,689	929	100,0	899	96,8	71,060	20,721
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	661	91,9	63,149	21,050	711	76,5	661	93,0	61,800	20,650
WEEK 13	Postmenopausal	842	90,2	797	94,7	61,972	21,773	864	93,0	820	94,9	60,711	20,916
WEEK 25	Postmenopausal	815	87,4	777	95,3	68,479	19,654	841	90,5	794	94,4	68,860	19,509
END OF TREATMENT	Postmenopausal	923	98,9	803	87,0	69,489	20,907	921	99,1	807	87,6	70,529	20,005
FU MONTH 18	Postmenopausal	839	89,9	754	89,9	73,044	20,106	844	90,9	726	86,0	72,016	20,126
FU MONTH 24	Postmenopausal	825	88,4	723	87,6	73,190	20,977	823	88,6	712	86,5	73,478	19,727
FU MONTH 36	Postmenopausal	801	85,9	714	89,1	74,895	19,542	776	83,5	676	87,1	72,448	21,149
BASELINE	Unknown/Missing	5	100,0	5	100,0	80,000	13,944	9	100,0	8	88,9	72,917	12,400
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	75,000	11,785	9	100,0	7	77,8	66,667	9,623
WEEK 13	Unknown/Missing	5	100,0	4	80,0	54,167	24,056	9	100,0	8	88,9	62,500	24,398
WEEK 25	Unknown/Missing	5	100,0	5	100,0	76,667	9,129	9	100,0	7	77,8	72,619	24,398
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	81,250	4,167	9	100,0	8	88,9	75,000	12,599
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	69,444	25,459	9	100,0	8	88,9	75,000	8,909
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	77,083	10,486	8	88,9	5	62,5	76,667	16,029
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	89,583	7,979	7	77,8	6	85,7	69,444	19,484
Age II													
BASELINE	< 65	1581	100,0	1537	97,2	72,457	19,798	1604	100,0	1567	97,7	72,559	19,149
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	65,685	19,754	1287	80,2	1221	94,9	64,565	19,761
WEEK 13	< 65	1497	94,7	1425	95,2	62,766	20,585	1529	95,3	1455	95,2	62,514	20,252

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1397	95,4	68,611	19,690	1501	93,6	1427	95,1	69,429	18,808
END OF TREATMENT	< 65	1569	99,2	1382	88,1	71,726	19,916	1596	99,5	1443	90,4	72,107	19,610
FU MONTH 18	< 65	1474	93,2	1311	88,9	74,809	19,232	1497	93,3	1316	87,9	73,227	19,334
FU MONTH 24	< 65	1446	91,5	1262	87,3	75,449	19,774	1450	90,4	1266	87,3	74,888	18,839
FU MONTH 36	< 65	1390	87,9	1232	88,6	76,738	19,481	1383	86,2	1200	86,8	74,604	19,799
BASELINE	>= 65	230	100,0	219	95,2	71,309	20,952	219	100,0	208	95,0	70,152	22,227
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	60,977	22,432	159	72,6	140	88,1	61,905	21,466
WEEK 13	>= 65	191	83,0	180	94,2	58,796	22,762	196	89,5	182	92,9	62,546	20,854
WEEK 25	>= 65	181	78,7	178	98,3	69,897	17,675	187	85,4	173	92,5	69,798	20,536
END OF TREATMENT	>= 65	225	97,8	188	83,6	66,755	23,570	215	98,2	182	84,7	73,581	20,278
FU MONTH 18	>= 65	189	82,2	170	89,9	71,078	20,795	191	87,2	155	81,2	74,140	18,950
FU MONTH 24	>= 65	187	81,3	169	90,4	73,323	20,605	188	85,8	156	83,0	72,329	20,932
FU MONTH 36	>= 65	181	78,7	158	87,3	73,207	19,076	173	79,0	148	85,5	72,410	21,819
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	72,581	22,173	24	100,0	24	100,0	78,125	15,699
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	61,765	23,210	17	70,8	16	94,1	63,021	23,564
WEEK 13	Grade 1	31	96,9	30	96,8	58,056	24,121	23	95,8	22	95,7	69,697	20,011
WEEK 25	Grade 1	31	96,9	28	90,3	63,988	24,851	23	95,8	22	95,7	69,697	18,642
END OF TREATMENT	Grade 1	31	96,9	27	87,1	70,988	24,171	24	100,0	22	91,7	69,697	23,365
FU MONTH 18	Grade 1	30	93,8	27	90,0	71,296	27,863	23	95,8	22	95,7	71,970	15,547
FU MONTH 24	Grade 1	28	87,5	27	96,4	74,691	23,053	23	95,8	21	91,3	73,810	21,129
FU MONTH 36	Grade 1	27	84,4	26	96,3	75,962	26,701	22	91,7	20	90,9	72,500	18,751
BASELINE	Grade 2	552	100,0	534	96,7	73,237	19,015	557	100,0	542	97,3	71,125	19,964
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	65,682	19,907	446	80,1	424	95,1	64,347	18,377

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	63,454	20,104	524	94,1	504	96,2	62,649	20,614
WEEK 25	Grade 2	494	89,5	477	96,6	69,672	18,844	515	92,5	491	95,3	70,010	18,373
END OF TREATMENT	Grade 2	548	99,3	485	88,5	71,821	20,838	553	99,3	495	89,5	72,071	19,333
FU MONTH 18	Grade 2	507	91,8	456	89,9	75,640	18,754	517	92,8	446	86,3	73,673	19,656
FU MONTH 24	Grade 2	501	90,8	448	89,4	75,279	20,679	500	89,8	431	86,2	73,473	19,284
FU MONTH 36	Grade 2	487	88,2	438	89,9	77,854	19,507	476	85,5	413	86,8	74,072	19,426
BASELINE	Grade 3	1161	100,0	1128	97,2	71,735	20,201	1173	100,0	1142	97,4	72,855	19,209
END OF ANTHRACYCLINE	Grade 3	918	79,1	854	93,0	64,998	20,027	919	78,3	859	93,5	64,474	20,560
WEEK 13	Grade 3	1088	93,7	1029	94,6	62,059	20,900	1114	95,0	1051	94,3	62,512	20,018
WEEK 25	Grade 3	1059	91,2	1012	95,6	68,256	19,434	1087	92,7	1025	94,3	69,057	19,312
END OF TREATMENT	Grade 3	1150	99,1	997	86,7	70,821	19,973	1165	99,3	1048	90,0	72,567	19,817
FU MONTH 18	Grade 3	1067	91,9	944	88,5	73,808	19,200	1085	92,5	945	87,1	73,422	19,023
FU MONTH 24	Grade 3	1046	90,1	902	86,2	75,046	19,268	1053	89,8	914	86,8	75,328	18,925
FU MONTH 36	Grade 3	1002	86,3	874	87,2	75,610	19,144	999	85,2	864	86,5	74,672	20,295
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	74,735	21,791	69	100,0	67	97,1	69,652	22,318
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	65,104	22,457	64	92,8	62	96,9	61,694	21,042
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	59,836	24,320	64	92,8	60	93,8	58,889	22,647
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	72,270	21,875	63	91,3	62	98,4	71,909	18,861
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	70,765	23,354	69	100,0	60	87,0	69,722	19,038
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	75,309	24,009	63	91,3	58	92,1	69,540	21,940

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	77,315	21,864	62	89,9	56	90,3	71,875	19,304
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	75,962	20,053	59	85,5	51	86,4	72,222	21,257
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	701	96,3	73,300	19,477	715	100,0	686	95,9	73,384	19,667
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	545	92,1	66,575	19,989	572	80,0	523	91,4	64,213	19,617
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	61,854	21,553	673	94,1	633	94,1	61,453	20,467
WEEK 25	Breast conserving surgery	665	91,3	634	95,3	67,495	20,040	654	91,5	614	93,9	68,526	19,289
END OF TREATMENT	Breast conserving surgery	722	99,2	622	86,1	70,820	20,438	711	99,4	622	87,5	72,093	19,497
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	73,735	19,484	659	92,2	557	84,5	73,444	18,915
FU MONTH 24	Breast conserving surgery	666	91,5	575	86,3	74,333	20,211	644	90,1	553	85,9	74,804	19,011
FU MONTH 36	Breast conserving surgery	651	89,4	561	86,2	76,679	18,767	616	86,2	535	86,9	74,283	19,500
BASELINE	Mastectomy	1083	100,0	1055	97,4	71,659	20,230	1107	100,0	1088	98,3	71,599	19,439
END OF ANTHRACYCLINE	Mastectomy	840	77,6	797	94,9	64,220	20,140	873	78,9	837	95,9	64,357	20,174
WEEK 13	Mastectomy	1011	93,4	966	95,5	62,629	20,411	1051	94,9	1003	95,4	63,169	20,198
WEEK 25	Mastectomy	980	90,5	941	96,0	69,607	19,043	1033	93,3	985	95,4	70,059	18,807
END OF TREATMENT	Mastectomy	1072	99,0	948	88,4	71,334	20,455	1099	99,3	1002	91,2	72,405	19,807
FU MONTH 18	Mastectomy	985	91,0	888	90,2	74,812	19,421	1028	92,9	913	88,8	73,275	19,520
FU MONTH 24	Mastectomy	967	89,3	856	88,5	75,779	19,643	993	89,7	868	87,4	74,510	19,141

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	76,106	19,925	939	84,8	813	86,6	74,416	20,389
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	642	97,3	71,924	20,321	665	100,0	641	96,4	72,998	19,125
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	481	92,7	65,211	19,452	523	78,6	492	94,1	63,127	19,687
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	61,401	20,736	631	94,9	606	96,0	61,991	19,944
WEEK 25	0 - < 2 cm	608	92,1	579	95,2	68,638	19,270	617	92,8	587	95,1	69,350	18,223
END OF TREATMENT	0 - < 2 cm	655	99,2	575	87,8	71,203	19,653	661	99,4	597	90,3	73,088	18,912
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	74,479	18,471	624	93,8	557	89,3	73,489	19,119
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	75,827	19,024	606	91,1	529	87,3	74,811	19,031
FU MONTH 36	0 - < 2 cm	596	90,3	524	87,9	77,067	18,757	580	87,2	506	87,2	75,214	20,109
BASELINE	>= 2 - < 5 cm	1009	100,0	975	96,6	72,778	19,260	991	100,0	969	97,8	71,801	19,783
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	753	94,5	65,018	20,243	789	79,6	743	94,2	64,614	19,925
WEEK 13	>= 2 - < 5 cm	935	92,7	894	95,6	62,864	20,771	940	94,9	889	94,6	62,317	20,504
WEEK 25	>= 2 - < 5 cm	910	90,2	876	96,3	68,969	19,581	919	92,7	866	94,2	69,178	19,409
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	867	86,9	71,617	20,340	985	99,4	875	88,8	71,648	19,744

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	827	89,6	74,365	19,950	914	92,2	782	85,6	72,869	19,007
FU MONTH 24	>= 2 - < 5 cm	905	89,7	783	86,5	74,936	20,338	889	89,7	775	87,2	74,161	19,096
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	75,766	20,105	839	84,7	725	86,4	73,368	20,177
BASELINE	>= 5 cm	139	100,0	137	98,6	70,499	22,710	165	100,0	163	98,8	72,495	19,513
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	66,111	22,026	132	80,0	124	93,9	66,734	21,052
WEEK 13	>= 5 cm	130	93,5	124	95,4	62,769	21,995	152	92,1	140	92,1	66,131	20,588
WEEK 25	>= 5 cm	124	89,2	117	94,4	67,664	19,731	150	90,9	145	96,7	72,069	19,333
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	67,533	24,130	163	98,8	151	92,6	72,848	22,225
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	74,065	20,455	148	89,7	130	87,8	75,449	21,298
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	73,724	20,725	141	85,5	116	82,3	77,443	18,423
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	77,063	17,966	135	81,8	115	85,2	77,174	18,506
BASELINE	Missing	3	100,0	2	66,7	95,833	5,893	2	100,0	2	100,0	54,167	41,248
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	66,667	28,868	2	100,0	2	100,0	79,167	5,893
WEEK 13	Missing	3	100,0	3	100,0	61,111	34,694	2	100,0	2	100,0	58,333	11,785
WEEK 25	Missing	3	100,0	3	100,0	72,222	25,459	2	100,0	2	100,0	41,667	11,785
END OF TREATMENT	Missing	3	100,0	3	100,0	66,667	28,868	2	100,0	2	100,0	58,333	11,785
FU MONTH 18	Missing	3	100,0	3	100,0	72,222	25,459	2	100,0	2	100,0	66,667	47,140
FU MONTH 24	Missing	3	100,0	3	100,0	86,111	17,347	2	100,0	2	100,0	29,167	5,893
FU MONTH 36	Missing	3	100,0	3	100,0	69,444	26,788	2	100,0	2	100,0	58,333	11,785
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1315	97,6	72,858	19,876	1350	100,0	1311	97,1	72,864	19,343
END OF ANTHRACYCLINE	Yes	1103	81,9	1046	94,8	65,942	19,853	1104	81,8	1042	94,4	64,851	19,727
WEEK 13	Yes	1308	97,1	1243	95,0	62,597	20,949	1324	98,1	1249	94,3	62,537	20,072
WEEK 25	Yes	1277	94,8	1219	95,5	68,437	19,577	1302	96,4	1228	94,3	69,490	19,149

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1210	89,8	70,992	20,254	1350	100,0	1234	91,4	72,650	19,329
FU MONTH 18	Yes	1291	95,8	1142	88,5	73,964	19,253	1298	96,1	1129	87,0	73,605	19,206
FU MONTH 24	Yes	1266	94,0	1109	87,6	74,662	19,920	1260	93,3	1087	86,3	74,632	19,014
FU MONTH 36	Yes	1219	90,5	1060	87,0	76,274	19,440	1195	88,5	1033	86,4	74,435	19,829
BASELINE	No	464	100,0	441	95,0	70,692	20,078	473	100,0	464	98,1	70,618	20,026
END OF ANTHRACYCLINE	No	329	70,9	296	90,0	62,472	20,778	342	72,3	319	93,3	62,461	20,592
WEEK 13	No	380	81,9	362	95,3	61,372	20,599	401	84,8	388	96,8	62,457	21,100
WEEK 25	No	368	79,3	356	96,7	69,850	19,096	386	81,6	372	96,4	69,400	18,508
END OF TREATMENT	No	447	96,3	360	80,5	71,597	21,088	461	97,5	391	84,8	71,078	20,747
FU MONTH 18	No	372	80,2	339	91,1	75,787	20,052	390	82,5	342	87,7	72,393	19,564
FU MONTH 24	No	367	79,1	322	87,7	77,045	19,654	378	79,9	335	88,6	74,527	19,356
FU MONTH 36	No	352	75,9	330	93,8	76,540	19,555	361	76,3	315	87,3	74,127	20,722
Race													
BASELINE	White	1252	100,0	1202	96,0	71,984	19,945	1255	100,0	1216	96,9	72,307	19,516
END OF ANTHRACYCLINE	White	1010	80,7	930	92,1	65,484	19,416	1018	81,1	940	92,3	64,273	19,626
WEEK 13	White	1158	92,5	1084	93,6	62,438	20,445	1183	94,3	1097	92,7	62,603	20,071
WEEK 25	White	1120	89,5	1055	94,2	68,673	18,902	1150	91,6	1070	93,0	69,385	18,773
END OF TREATMENT	White	1238	98,9	1045	84,4	70,909	20,709	1244	99,1	1087	87,4	72,048	19,983
FU MONTH 18	White	1138	90,9	978	85,9	74,071	19,245	1152	91,8	964	83,7	73,323	18,587
FU MONTH 24	White	1115	89,1	941	84,4	75,151	19,956	1120	89,2	938	83,8	74,618	19,063
FU MONTH 36	White	1071	85,5	921	86,0	76,583	19,747	1064	84,8	895	84,1	74,432	20,073
BASELINE	Black	25	100,0	24	96,0	72,222	22,207	31	100,0	30	96,8	70,000	27,123
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	60,185	21,960	15	48,4	15	100,0	58,333	18,898
WEEK 13	Black	21	84,0	17	81,0	66,667	17,678	29	93,5	28	96,6	68,155	18,433

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	70,614	16,285	29	93,5	28	96,6	69,048	23,002
END OF TREATMENT	Black	24	96,0	22	91,7	71,212	20,205	31	100,0	27	87,1	74,383	17,284
FU MONTH 18	Black	23	92,0	17	73,9	71,569	19,995	29	93,5	24	82,8	62,500	27,474
FU MONTH 24	Black	22	88,0	18	81,8	70,370	21,241	28	90,3	23	82,1	76,812	19,777
FU MONTH 36	Black	22	88,0	18	81,8	76,389	18,798	26	83,9	20	76,9	75,000	24,031
BASELINE	Asian	477	100,0	473	99,2	72,216	20,075	484	100,0	478	98,8	71,688	19,465
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	63,897	21,427	375	77,5	368	98,1	64,221	20,506
WEEK 13	Asian	455	95,4	450	98,9	61,259	22,200	466	96,3	465	99,8	61,093	21,009
WEEK 25	Asian	450	94,3	448	99,6	68,080	20,980	465	96,1	459	98,7	69,099	19,496
END OF TREATMENT	Asian	475	99,6	452	95,2	70,999	19,811	484	100,0	463	95,7	72,264	18,922
FU MONTH 18	Asian	447	93,7	433	96,9	74,788	19,767	461	95,2	442	95,9	73,171	20,326
FU MONTH 24	Asian	442	92,7	423	95,7	74,645	20,019	445	91,9	420	94,4	73,790	19,269
FU MONTH 36	Asian	424	88,9	402	94,8	75,021	18,865	425	87,8	398	93,6	73,639	19,990
BASELINE	Other	52	100,0	52	100,0	81,090	16,429	51	100,0	50	98,0	78,333	14,580
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	72,297	21,251	36	70,6	36	100,0	67,130	23,312
WEEK 13	Other	49	94,2	49	100,0	67,857	18,556	45	88,2	45	100,0	71,111	17,820
WEEK 25	Other	49	94,2	48	98,0	75,000	18,029	42	82,4	41	97,6	74,797	15,194
END OF TREATMENT	Other	52	100,0	47	90,4	76,596	20,533	50	98,0	47	94,0	76,241	21,632
FU MONTH 18	Other	50	96,2	48	96,0	78,472	20,400	44	86,3	39	88,6	80,983	15,288
FU MONTH 24	Other	49	94,2	45	91,8	83,148	15,127	43	84,3	39	90,7	81,197	16,525
FU MONTH 36	Other	49	94,2	44	89,8	82,008	18,057	39	76,5	33	84,6	80,051	16,659
BASELINE	Missing	5	100,0	5	100,0	70,000	13,944	2	100,0	1	50,0	83,333	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	56,667	28,504	2	100,0	2	100,0	79,167	5,893
WEEK 13	Missing	5	100,0	5	100,0	63,333	13,944	2	100,0	2	100,0	75,000	11,785

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	80,000	12,638	2	100,0	2	100,0	95,833	5,893
END OF TREATMENT	Missing	5	100,0	4	80,0	79,167	20,972	2	100,0	1	50,0	75,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	70,000	21,731	2	100,0	2	100,0	87,500	17,678
FU MONTH 24	Missing	5	100,0	4	80,0	77,083	12,500	2	100,0	2	100,0	87,500	17,678
FU MONTH 36	Missing	5	100,0	5	100,0	86,667	21,731	2	100,0	2	100,0	87,500	17,678

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_GLHST_SG.xls
11AUG2020 16:04

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Physical Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1764	97,4	89,255	12,792	1823	100,0	1779	97,6	88,815	13,493
END OF ANTHRACYCLINE	n/a	1432	79,1	1346	94,0	83,810	15,688	1446	79,3	1363	94,3	82,577	15,780
WEEK 13	n/a	1688	93,2	1607	95,2	79,288	17,746	1725	94,6	1638	95,0	78,618	18,327
WEEK 25	n/a	1645	90,8	1585	96,4	85,095	15,104	1688	92,6	1602	94,9	84,994	15,204
END OF TREATMENT	n/a	1794	99,1	1576	87,8	86,202	15,204	1811	99,3	1630	90,0	86,662	15,498
FU MONTH 18	n/a	1663	91,8	1486	89,4	88,374	13,869	1688	92,6	1478	87,6	87,941	14,942
FU MONTH 24	n/a	1633	90,2	1433	87,8	89,272	13,396	1638	89,9	1427	87,1	88,857	14,105
FU MONTH 36	n/a	1571	86,7	1392	88,6	89,549	13,831	1556	85,4	1356	87,1	89,183	13,935
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	92,177	9,117	43	100,0	40	93,0	88,333	15,154
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	84,946	14,398	26	60,5	25	96,2	81,067	18,427
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	79,470	15,945	40	93,0	39	97,5	78,120	18,286
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	83,566	15,143	38	88,4	35	92,1	82,286	17,708
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	90,303	9,693	42	97,7	37	88,1	88,288	13,463
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	91,938	12,646	39	90,7	36	92,3	87,130	16,981

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	93,333	9,085	39	90,7	34	87,2	89,804	11,160
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	89,481	13,218	39	90,7	37	94,9	89,910	11,506
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	90,503	12,522	278	100,0	271	97,5	90,720	11,536
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	85,262	13,570	203	73,0	191	94,1	83,368	15,198
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	79,270	17,814	263	94,6	252	95,8	78,161	17,527
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	85,203	14,727	256	92,1	247	96,5	85,533	14,167
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	87,137	14,430	276	99,3	255	92,4	87,765	14,545
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	89,273	13,367	259	93,2	233	90,0	88,784	13,931
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	90,630	11,558	256	92,1	230	89,8	90,630	12,439
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	90,868	13,168	251	90,3	227	90,4	90,323	14,390
BASELINE	1-3 positive nodes	907	100,0	886	97,7	90,310	11,965	900	100,0	878	97,6	88,806	13,373
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	665	93,3	84,997	15,087	707	78,6	668	94,5	82,315	15,538
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	79,620	17,478	854	94,9	806	94,4	78,639	18,398
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	85,968	14,825	836	92,9	789	94,4	85,135	14,843
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	86,684	14,666	897	99,7	814	90,7	86,519	15,664
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	88,891	13,155	852	94,7	746	87,6	88,059	14,450

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	89,595	13,222	830	92,2	727	87,6	88,670	14,186
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	90,045	13,653	794	88,2	671	84,5	89,071	14,111
BASELINE	>= 4 positive nodes	596	100,0	577	96,8	86,842	14,024	602	100,0	590	98,0	87,986	14,308
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	81,515	17,069	510	84,7	479	93,9	82,707	16,225
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	78,770	18,295	568	94,4	541	95,2	78,835	18,631
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	83,843	15,630	558	92,7	531	95,2	84,711	16,021
END OF TREATMENT	>= 4 positive nodes	590	99,0	522	88,5	84,729	16,539	596	99,0	524	87,9	86,231	15,827
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	86,863	15,092	538	89,4	463	86,1	87,390	16,032
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	87,741	14,605	513	85,2	436	85,0	88,157	14,939
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	88,072	14,420	472	78,4	421	89,2	88,683	13,603
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1404	97,6	89,428	12,687	1448	100,0	1413	97,6	88,988	13,306
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1344	94,1	83,791	15,691	1444	99,7	1362	94,3	82,589	15,780
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	80,004	17,328	1374	94,9	1303	94,8	79,250	17,915
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	85,402	14,952	1346	93,0	1277	94,9	85,610	15,003
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1260	88,2	86,386	15,067	1444	99,7	1306	90,4	86,565	15,738

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1185	89,2	88,601	13,653	1340	92,5	1182	88,2	88,158	14,962
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	89,305	13,367	1308	90,3	1138	87,0	88,935	14,287
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	89,506	13,944	1244	85,9	1090	87,6	89,266	14,135
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	88,580	13,191	375	100,0	366	97,6	88,147	14,191
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	96,667	4,714	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	76,353	19,114	351	93,6	335	95,4	76,159	19,684
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	83,906	15,642	342	91,2	325	95,0	82,574	15,761
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	85,469	15,740	367	97,9	324	88,3	87,052	14,509
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	87,481	14,677	348	92,8	296	85,1	87,072	14,854
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	89,138	13,535	330	88,0	289	87,6	88,547	13,387
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	89,715	13,396	312	83,2	266	85,3	88,843	13,106
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	843	97,6	88,969	13,140	858	100,0	840	97,9	89,214	12,578
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	638	94,9	83,699	15,407	661	77,0	621	93,9	82,484	15,437
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	79,027	17,847	804	93,7	772	96,0	78,709	17,512
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	84,677	14,560	786	91,6	750	95,4	85,098	14,423
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	766	89,5	86,171	14,659	854	99,5	766	89,7	87,017	14,841
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	719	89,8	88,519	13,412	781	91,0	697	89,2	88,355	14,369
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	89,724	12,373	763	88,9	676	88,6	89,549	13,050
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	89,700	13,335	735	85,7	656	89,3	89,808	13,166
BASELINE	Positive (ER and/or PgR positive)	947	100,0	921	97,3	89,517	12,467	965	100,0	939	97,3	88,458	14,259
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	708	93,2	83,910	15,947	785	81,3	742	94,5	82,655	16,071
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	79,532	17,657	921	95,4	866	94,0	78,537	19,033
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	85,494	15,604	902	93,5	852	94,5	84,902	15,867
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	86,233	15,711	957	99,2	864	90,3	86,346	16,061
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	88,238	14,292	907	94,0	781	86,1	87,571	15,435
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	88,848	14,286	875	90,7	751	85,8	88,233	14,973

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	89,405	14,293	821	85,1	700	85,3	88,598	14,604
Geographical region II													
BASELINE	USA/Canada	265	100,0	260	98,1	90,573	13,171	260	100,0	255	98,1	89,261	14,749
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	85,948	16,462	111	42,7	105	94,6	83,714	16,325
WEEK 13	USA/Canada	242	91,3	229	94,6	77,693	20,705	236	90,8	224	94,9	77,738	20,430
WEEK 25	USA/Canada	234	88,3	225	96,2	85,719	15,682	230	88,5	219	95,2	85,145	16,886
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	87,389	16,456	255	98,1	229	89,8	86,434	17,878
FU MONTH 18	USA/Canada	238	89,8	194	81,5	88,763	16,101	231	88,8	181	78,4	88,867	15,242
FU MONTH 24	USA/Canada	231	87,2	188	81,4	89,752	15,000	224	86,2	177	79,0	89,981	14,055
FU MONTH 36	USA/Canada	223	84,2	180	80,7	90,759	14,557	205	78,8	156	76,1	91,132	12,319
BASELINE	Western Europe	827	100,0	790	95,5	90,224	12,820	822	100,0	787	95,7	90,546	13,652
END OF ANTHRACYCLINE	Western Europe	732	88,5	668	91,3	83,069	16,845	728	88,6	664	91,2	82,464	16,967
WEEK 13	Western Europe	764	92,4	700	91,6	78,654	18,101	778	94,6	710	91,3	77,876	19,488
WEEK 25	Western Europe	738	89,2	693	93,9	84,649	16,209	750	91,2	681	90,8	85,149	16,187
END OF TREATMENT	Western Europe	821	99,3	695	84,7	85,139	17,048	817	99,4	705	86,3	86,352	16,584
FU MONTH 18	Western Europe	754	91,2	650	86,2	87,608	15,314	764	92,9	632	82,7	87,751	16,079
FU MONTH 24	Western Europe	739	89,4	614	83,1	88,602	14,879	747	90,9	621	83,1	88,833	14,828
FU MONTH 36	Western Europe	713	86,2	613	86,0	88,839	15,212	712	86,6	601	84,4	88,811	15,077
BASELINE	Asia Pacific	490	100,0	487	99,4	87,426	12,179	512	100,0	508	99,2	86,850	12,399
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	84,991	13,146	397	77,5	390	98,2	83,094	13,329
WEEK 13	Asia Pacific	466	95,1	465	99,8	80,086	15,974	493	96,3	492	99,8	80,014	15,590
WEEK 25	Asia Pacific	461	94,1	461	100,0	85,756	13,049	492	96,1	488	99,2	85,669	11,940

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	87,313	12,208	512	100,0	491	95,9	88,337	11,704
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	89,676	10,599	485	94,7	473	97,5	88,964	12,596
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	90,733	9,924	470	91,8	448	95,3	89,792	11,989
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	90,534	11,016	453	88,5	432	95,4	89,842	12,561
BASELINE	Latin America	43	100,0	43	100,0	91,938	8,042	47	100,0	47	100,0	88,794	11,967
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	89,195	11,874	32	68,1	32	100,0	85,833	16,483
WEEK 13	Latin America	40	93,0	40	100,0	85,000	15,451	44	93,6	44	100,0	80,455	18,095
WEEK 25	Latin America	39	90,7	39	100,0	89,915	10,245	44	93,6	44	100,0	86,970	12,776
END OF TREATMENT	Latin America	42	97,7	38	90,5	91,228	9,568	45	95,7	42	93,3	89,365	11,506
FU MONTH 18	Latin America	41	95,3	37	90,2	91,532	10,960	42	89,4	40	95,2	88,667	13,771
FU MONTH 24	Latin America	40	93,0	36	90,0	94,259	10,709	41	87,2	39	95,1	90,598	11,105
FU MONTH 36	Latin America	38	88,4	34	89,5	92,745	9,337	37	78,7	36	97,3	89,861	10,797
BASELINE	Other	186	100,0	184	98,9	87,446	13,902	182	100,0	182	100,0	86,190	13,260
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	81,956	15,845	178	97,8	172	96,6	80,543	15,621
WEEK 13	Other	176	94,6	173	98,3	80,501	16,798	174	95,6	168	96,6	78,363	17,709
WEEK 25	Other	173	93,0	167	96,5	83,154	15,554	172	94,5	170	98,8	81,725	17,380
END OF TREATMENT	Other	185	99,5	162	87,6	84,815	13,318	182	100,0	163	89,6	82,577	17,171
FU MONTH 18	Other	171	91,9	153	89,5	86,525	13,168	166	91,2	152	91,6	84,254	16,231
FU MONTH 24	Other	169	90,9	154	91,1	86,006	13,545	156	85,7	142	91,0	84,131	16,801
FU MONTH 36	Other	160	86,0	147	91,9	87,483	14,595	149	81,9	131	87,9	86,209	14,957
Protocol version													
BASELINE	Protocol A	1240	100,0	1208	97,4	89,582	12,647	1246	100,0	1212	97,3	89,432	12,522

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	917	93,2	84,331	15,362	988	79,3	929	94,0	82,751	15,420
WEEK 13	Protocol A	1155	93,1	1108	95,9	79,545	17,622	1180	94,7	1113	94,3	78,613	17,903
WEEK 25	Protocol A	1125	90,7	1087	96,6	85,457	14,983	1157	92,9	1093	94,5	85,317	14,856
END OF TREATMENT	Protocol A	1229	99,1	1075	87,5	86,778	15,095	1236	99,2	1117	90,4	87,240	15,014
FU MONTH 18	Protocol A	1142	92,1	1026	89,8	88,533	14,026	1156	92,8	1007	87,1	88,350	14,309
FU MONTH 24	Protocol A	1124	90,6	995	88,5	89,389	13,305	1127	90,4	982	87,1	89,197	13,873
FU MONTH 36	Protocol A	1087	87,7	980	90,2	89,762	13,688	1069	85,8	938	87,7	89,551	13,743
BASELINE	Protocol Amendment B	571	100,0	556	97,4	88,544	13,084	577	100,0	567	98,3	87,496	15,293
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	82,696	16,325	458	79,4	434	94,8	82,204	16,535
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	78,717	18,021	545	94,5	525	96,3	78,629	19,212
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	84,304	15,350	531	92,0	509	95,9	84,299	15,917
END OF TREATMENT	Protocol Amendment B	565	98,9	501	88,7	84,967	15,377	575	99,7	513	89,2	85,403	16,448
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	88,018	13,522	532	92,2	471	88,5	87,067	16,194
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	89,007	13,613	511	88,6	445	87,1	88,105	14,593
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	89,041	14,168	487	84,4	418	85,8	88,357	14,339
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	90,775	12,037	321	100,0	311	96,9	90,413	12,059
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	85,215	13,661	229	71,3	216	94,3	83,102	15,575
WEEK 13	0 positive nodes	294	95,5	279	94,9	79,301	17,505	303	94,4	291	96,0	78,156	17,599
WEEK 25	0 positive nodes	287	93,2	281	97,9	84,953	14,776	294	91,6	282	95,9	85,130	14,656
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	87,651	13,807	318	99,1	292	91,8	87,831	14,392
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	89,708	13,265	298	92,8	269	90,3	88,563	14,352

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	91,091	11,205	295	91,9	264	89,5	90,524	12,265
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	90,628	13,161	290	90,3	264	91,0	90,265	14,003
BASELINE	>= 1 positive nodes	1503	100,0	1463	97,3	88,942	12,924	1502	100,0	1468	97,7	88,476	13,758
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1137	94,0	83,552	16,024	1217	81,0	1147	94,2	82,478	15,823
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	79,285	17,802	1422	94,7	1347	94,7	78,718	18,485
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	85,125	15,179	1394	92,8	1320	94,7	84,965	15,323
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1305	87,6	85,902	15,466	1493	99,4	1338	89,6	86,406	15,723
FU MONTH 18	>= 1 positive nodes	1371	91,2	1223	89,2	88,087	13,984	1390	92,5	1209	87,0	87,803	15,072
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	88,884	13,792	1343	89,4	1163	86,6	88,478	14,469
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	89,301	13,974	1266	84,3	1092	86,3	88,921	13,912
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	854	97,8	89,957	12,374	885	100,0	868	98,1	90,378	11,875
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	84,879	14,844	726	82,0	693	95,5	85,108	14,183
WEEK 13	Premenopausal	841	96,3	806	95,8	80,922	16,243	852	96,3	809	95,0	81,183	16,730
WEEK 25	Premenopausal	825	94,5	800	97,0	86,371	14,475	838	94,7	799	95,3	87,637	13,088
END OF TREATMENT	Premenopausal	866	99,2	766	88,5	88,466	13,521	881	99,5	812	92,2	89,265	13,486
FU MONTH 18	Premenopausal	819	93,8	724	88,4	90,612	12,299	835	94,4	740	88,6	90,586	12,455
FU MONTH 24	Premenopausal	803	92,0	705	87,8	91,357	11,852	807	91,2	708	87,7	91,069	12,358

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	91,637	12,919	773	87,3	670	86,7	91,871	11,378
BASELINE	Postmenopausal	933	100,0	905	97,0	88,541	13,159	929	100,0	903	97,2	87,316	14,734
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	666	92,6	82,675	16,447	711	76,5	663	93,2	79,949	16,908
WEEK 13	Postmenopausal	842	90,2	797	94,7	77,574	19,019	864	93,0	821	95,0	76,110	19,456
WEEK 25	Postmenopausal	815	87,4	780	95,7	83,733	15,645	841	90,5	796	94,6	82,385	16,628
END OF TREATMENT	Postmenopausal	923	98,9	806	87,3	84,041	16,392	921	99,1	810	87,9	84,093	16,905
FU MONTH 18	Postmenopausal	839	89,9	759	90,5	86,219	14,930	844	90,9	730	86,5	85,311	16,604
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	87,192	14,478	823	88,6	713	86,6	86,660	15,372
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	87,552	14,393	776	83,5	680	87,6	86,587	15,616
BASELINE	Unknown/Missing	5	100,0	5	100,0	98,667	2,981	9	100,0	8	88,9	88,333	14,584
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	90,667	13,824	9	100,0	7	77,8	80,952	16,523
WEEK 13	Unknown/Missing	5	100,0	4	80,0	91,667	10,000	9	100,0	8	88,9	76,667	19,841
WEEK 25	Unknown/Missing	5	100,0	5	100,0	93,333	6,667	9	100,0	7	77,8	80,000	20,000
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	88,333	8,389	9	100,0	8	88,9	82,500	15,092
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	93,333	6,667	9	100,0	8	88,9	83,333	23,094
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	98,333	3,333	8	88,9	6	75,0	88,889	10,887
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	95,000	6,383	7	77,8	6	85,7	83,333	16,193
Age II													
BASELINE	< 65	1581	100,0	1544	97,7	89,411	12,639	1604	100,0	1571	97,9	89,287	12,853
END OF ANTHRACYCLINE	< 65	1268	80,2	1198	94,5	84,338	15,359	1287	80,2	1221	94,9	83,101	15,261
WEEK 13	< 65	1497	94,7	1427	95,3	80,227	16,987	1529	95,3	1455	95,2	79,147	17,859

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	85,646	14,628	1501	93,6	1429	95,2	85,741	14,402
END OF TREATMENT	< 65	1569	99,2	1387	88,4	87,134	14,033	1596	99,5	1447	90,7	87,231	14,719
FU MONTH 18	< 65	1474	93,2	1314	89,1	88,899	13,493	1497	93,3	1321	88,2	88,385	14,532
FU MONTH 24	< 65	1446	91,5	1263	87,3	89,971	12,721	1450	90,4	1270	87,6	89,461	13,634
FU MONTH 36	< 65	1390	87,9	1234	88,8	90,296	13,062	1383	86,2	1207	87,3	89,711	13,569
BASELINE	>= 65	230	100,0	220	95,7	88,162	13,797	219	100,0	208	95,0	85,248	17,214
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	79,538	17,616	159	72,6	142	89,3	78,075	19,164
WEEK 13	>= 65	191	83,0	180	94,2	71,849	21,536	196	89,5	183	93,4	74,417	21,279
WEEK 25	>= 65	181	78,7	178	98,3	80,740	17,895	187	85,4	173	92,5	78,825	19,660
END OF TREATMENT	>= 65	225	97,8	189	84,0	79,365	20,767	215	98,2	183	85,1	82,158	20,139
FU MONTH 18	>= 65	189	82,2	172	91,0	84,360	15,944	191	87,2	157	82,2	84,204	17,643
FU MONTH 24	>= 65	187	81,3	170	90,9	84,078	16,778	188	85,8	157	83,5	83,970	16,723
FU MONTH 36	>= 65	181	78,7	158	87,3	83,713	17,782	173	79,0	149	86,1	84,903	16,024
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	88,817	14,338	24	100,0	24	100,0	89,722	13,758
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	79,804	23,347	17	70,8	16	94,1	78,750	21,667
WEEK 13	Grade 1	31	96,9	30	96,8	73,778	23,023	23	95,8	22	95,7	81,212	18,815
WEEK 25	Grade 1	31	96,9	29	93,5	79,770	22,712	23	95,8	22	95,7	85,455	14,784
END OF TREATMENT	Grade 1	31	96,9	27	87,1	86,420	13,772	24	100,0	21	87,5	87,302	15,478
FU MONTH 18	Grade 1	30	93,8	27	90,0	84,691	19,020	23	95,8	22	95,7	83,636	16,033
FU MONTH 24	Grade 1	28	87,5	27	96,4	87,407	14,945	23	95,8	21	91,3	85,079	18,124
FU MONTH 36	Grade 1	27	84,4	26	96,3	87,436	18,118	22	91,7	20	90,9	85,333	16,838
BASELINE	Grade 2	552	100,0	537	97,3	89,997	11,381	557	100,0	544	97,7	88,771	13,171
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	84,359	15,610	446	80,1	424	95,1	83,160	14,768

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	80,336	17,106	524	94,1	503	96,0	79,165	18,412
WEEK 25	Grade 2	494	89,5	479	97,0	85,971	14,652	515	92,5	493	95,7	85,494	14,805
END OF TREATMENT	Grade 2	548	99,3	485	88,5	86,526	15,767	553	99,3	496	89,7	86,821	15,642
FU MONTH 18	Grade 2	507	91,8	457	90,1	89,311	13,404	517	92,8	448	86,7	88,590	13,870
FU MONTH 24	Grade 2	501	90,8	449	89,6	89,796	13,162	500	89,8	431	86,2	89,250	14,079
FU MONTH 36	Grade 2	487	88,2	438	89,9	90,632	13,319	476	85,5	415	87,2	89,233	14,087
BASELINE	Grade 3	1161	100,0	1133	97,6	88,901	13,346	1173	100,0	1143	97,4	88,892	13,647
END OF ANTHRACYCLINE	Grade 3	918	79,1	857	93,4	83,403	15,632	919	78,3	861	93,7	82,353	16,254
WEEK 13	Grade 3	1088	93,7	1030	94,7	78,880	17,765	1114	95,0	1053	94,5	78,382	18,386
WEEK 25	Grade 3	1059	91,2	1019	96,2	84,771	14,910	1087	92,7	1025	94,3	84,675	15,528
END OF TREATMENT	Grade 3	1150	99,1	1003	87,2	86,039	14,859	1165	99,3	1053	90,4	86,649	15,434
FU MONTH 18	Grade 3	1067	91,9	948	88,8	88,005	13,824	1085	92,5	949	87,5	87,778	15,436
FU MONTH 24	Grade 3	1046	90,1	903	86,3	88,979	13,454	1053	89,8	919	87,3	88,712	14,022
FU MONTH 36	Grade 3	1002	86,3	876	87,4	88,959	13,868	999	85,2	869	87,0	89,214	13,902
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	89,524	13,210	69	100,0	68	98,6	87,549	13,575
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	87,639	13,683	64	92,8	62	96,9	82,688	14,153
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	80,546	19,141	64	92,8	60	93,8	77,222	16,527
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	86,207	17,071	63	91,3	62	98,4	86,129	13,074
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	86,230	17,078	69	100,0	60	87,0	85,333	15,757
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	88,765	15,314	63	91,3	59	93,7	87,232	14,292

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	90,741	13,670	62	89,9	56	90,3	89,613	14,146
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	91,410	14,662	59	85,5	52	88,1	89,744	12,133
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	706	97,0	90,770	12,542	715	100,0	687	96,1	90,306	13,494
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	548	92,6	84,373	16,072	572	80,0	523	91,4	83,004	15,734
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	78,233	18,719	673	94,1	633	94,1	77,083	19,320
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	84,113	16,596	654	91,5	613	93,7	83,994	16,606
END OF TREATMENT	Breast conserving surgery	722	99,2	625	86,6	85,627	16,348	711	99,4	622	87,5	85,592	16,739
FU MONTH 18	Breast conserving surgery	678	93,1	596	87,9	88,012	14,775	659	92,2	561	85,1	87,953	15,082
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	88,782	14,625	644	90,1	555	86,2	89,213	14,010
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	89,324	14,545	616	86,2	539	87,5	88,995	14,823
BASELINE	Mastectomy	1083	100,0	1058	97,7	88,244	12,863	1107	100,0	1091	98,6	87,878	13,420
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	83,423	15,416	873	78,9	839	96,1	82,362	15,754
WEEK 13	Mastectomy	1011	93,4	968	95,7	79,985	17,047	1051	94,9	1004	95,5	79,598	17,617
WEEK 25	Mastectomy	980	90,5	946	96,5	85,758	13,976	1033	93,3	988	95,6	85,639	14,222
END OF TREATMENT	Mastectomy	1072	99,0	951	88,7	86,581	14,399	1099	99,3	1007	91,6	87,375	14,559
FU MONTH 18	Mastectomy	985	91,0	890	90,4	88,616	13,231	1028	92,9	916	89,1	87,964	14,843
FU MONTH 24	Mastectomy	967	89,3	857	88,6	89,601	12,501	993	89,7	871	87,7	88,670	14,127

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	89,701	13,333	939	84,8	817	87,0	89,307	13,325
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	86,667	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	40,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	60,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	60,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	53,333	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	90,556	11,919	665	100,0	642	96,5	90,223	13,154
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	482	92,9	84,378	15,120	523	78,6	493	94,3	82,735	15,525
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	79,473	17,544	631	94,9	605	95,9	79,072	17,819
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	85,363	14,845	617	92,8	588	95,3	85,269	15,311
END OF TREATMENT	0 - < 2 cm	655	99,2	579	88,4	86,681	15,143	661	99,4	598	90,5	87,015	15,137
FU MONTH 18	0 - < 2 cm	617	93,5	546	88,5	89,100	13,636	624	93,8	561	89,9	88,375	15,094
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	90,097	13,351	606	91,1	531	87,6	89,799	13,696
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	90,359	12,923	580	87,2	508	87,6	89,925	14,038
BASELINE	>= 2 - < 5 cm	1009	100,0	980	97,1	88,739	13,020	991	100,0	972	98,1	88,009	13,765
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	756	94,9	83,651	16,014	789	79,6	744	94,3	81,885	16,220
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	79,222	17,805	940	94,9	891	94,8	77,611	18,890
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	84,888	15,176	919	92,7	865	94,1	84,597	15,283
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	869	87,1	85,946	15,263	985	99,4	878	89,1	86,450	15,527

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	88,197	13,826	914	92,2	785	85,9	87,234	15,127
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	88,800	13,539	889	89,7	777	87,4	88,067	14,433
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	89,262	14,180	839	84,7	730	87,0	88,523	14,010
BASELINE	>= 5 cm	139	100,0	137	98,6	86,667	14,485	165	100,0	163	98,8	88,303	12,573
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	82,206	15,974	132	80,0	124	93,9	86,304	13,407
WEEK 13	>= 5 cm	130	93,5	125	96,2	78,773	18,363	152	92,1	140	92,1	83,143	16,022
WEEK 25	>= 5 cm	124	89,2	119	96,0	85,378	15,749	150	90,9	147	98,0	86,474	14,017
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	85,707	15,210	163	98,8	152	93,3	86,842	16,419
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	86,090	15,016	148	89,7	130	87,8	90,410	12,725
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	88,468	12,583	141	85,5	117	83,0	89,915	13,437
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	87,591	15,320	135	81,8	116	85,9	90,249	12,810
BASELINE	Missing	3	100,0	2	66,7	100,000	0,000	2	100,0	2	100,0	70,000	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	88,889	13,878	2	100,0	2	100,0	70,000	23,570
WEEK 13	Missing	3	100,0	3	100,0	84,444	21,430	2	100,0	2	100,0	73,333	28,284
WEEK 25	Missing	3	100,0	3	100,0	82,222	25,240	2	100,0	2	100,0	66,667	28,284
END OF TREATMENT	Missing	3	100,0	3	100,0	88,889	13,878	2	100,0	2	100,0	60,000	28,284
FU MONTH 18	Missing	3	100,0	3	100,0	86,667	23,094	2	100,0	2	100,0	83,333	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	95,556	7,698	2	100,0	2	100,0	83,333	23,570
FU MONTH 36	Missing	3	100,0	3	100,0	86,667	23,094	2	100,0	2	100,0	80,000	18,856
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1321	98,1	89,568	12,817	1350	100,0	1314	97,3	89,324	13,519
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	84,168	15,830	1104	81,8	1044	94,6	83,007	15,837
WEEK 13	Yes	1308	97,1	1245	95,2	79,319	18,008	1324	98,1	1250	94,4	78,692	18,388
WEEK 25	Yes	1277	94,8	1227	96,1	85,141	15,406	1302	96,4	1229	94,4	85,115	15,636

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1214	90,1	86,037	15,578	1350	100,0	1237	91,6	86,762	15,457
FU MONTH 18	Yes	1291	95,8	1146	88,8	88,117	14,429	1298	96,1	1134	87,4	88,142	15,089
FU MONTH 24	Yes	1266	94,0	1110	87,7	88,997	13,799	1260	93,3	1092	86,7	88,857	14,246
FU MONTH 36	Yes	1219	90,5	1062	87,1	89,402	14,079	1195	88,5	1040	87,0	89,081	14,044
BASELINE	No	464	100,0	443	95,5	88,323	12,685	473	100,0	465	98,3	87,376	13,330
END OF ANTHRACYCLINE	No	329	70,9	298	90,6	82,550	15,136	342	72,3	319	93,3	81,170	15,532
WEEK 13	No	380	81,9	362	95,3	79,184	16,835	401	84,8	388	96,8	78,381	18,149
WEEK 25	No	368	79,3	358	97,3	84,935	14,038	386	81,6	373	96,6	84,593	13,695
END OF TREATMENT	No	447	96,3	362	81,0	86,759	13,880	461	97,5	393	85,2	86,344	15,642
FU MONTH 18	No	372	80,2	340	91,4	89,240	11,766	390	82,5	344	88,2	87,277	14,449
FU MONTH 24	No	367	79,1	323	88,0	90,217	11,879	378	79,9	335	88,6	88,856	13,658
FU MONTH 36	No	352	75,9	330	93,8	90,020	13,008	361	76,3	316	87,5	89,520	13,586
Race													
BASELINE	White	1252	100,0	1208	96,5	90,016	13,066	1255	100,0	1217	97,0	90,001	13,538
END OF ANTHRACYCLINE	White	1010	80,7	933	92,4	83,616	16,281	1018	81,1	942	92,5	82,602	16,463
WEEK 13	White	1158	92,5	1086	93,8	79,057	18,251	1183	94,3	1098	92,8	77,866	19,499
WEEK 25	White	1120	89,5	1063	94,9	84,831	16,145	1150	91,6	1072	93,2	84,857	16,410
END OF TREATMENT	White	1238	98,9	1051	84,9	85,737	16,400	1244	99,1	1090	87,6	85,943	16,934
FU MONTH 18	White	1138	90,9	982	86,3	88,009	14,767	1152	91,8	969	84,1	87,551	15,892
FU MONTH 24	White	1115	89,1	943	84,6	88,667	14,462	1120	89,2	942	84,1	88,455	14,934
FU MONTH 36	White	1071	85,5	923	86,2	89,103	14,902	1064	84,8	903	84,9	88,888	14,622
BASELINE	Black	25	100,0	24	96,0	86,389	12,508	31	100,0	30	96,8	82,333	16,263
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	80,000	11,547	15	48,4	15	100,0	80,000	16,903
WEEK 13	Black	21	84,0	17	81,0	75,294	17,443	29	93,5	28	96,6	77,857	17,026

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	82,456	15,747	29	93,5	28	96,6	79,524	15,601
END OF TREATMENT	Black	24	96,0	22	91,7	83,333	14,365	31	100,0	28	90,3	83,095	18,188
FU MONTH 18	Black	23	92,0	17	73,9	83,137	16,519	29	93,5	24	82,8	80,000	17,802
FU MONTH 24	Black	22	88,0	18	81,8	90,000	13,185	28	90,3	23	82,1	83,768	18,838
FU MONTH 36	Black	22	88,0	18	81,8	88,519	17,535	26	83,9	20	76,9	81,667	18,337
BASELINE	Asian	477	100,0	475	99,6	87,256	12,196	484	100,0	480	99,2	86,208	12,709
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	84,695	13,683	375	77,5	368	98,1	82,577	13,408
WEEK 13	Asian	455	95,4	450	98,9	79,911	16,226	466	96,3	465	99,8	79,828	15,249
WEEK 25	Asian	450	94,3	449	99,8	85,494	12,500	465	96,1	459	98,7	85,229	12,104
END OF TREATMENT	Asian	475	99,6	452	95,2	87,032	12,147	484	100,0	464	95,9	88,075	11,672
FU MONTH 18	Asian	447	93,7	434	97,1	89,370	11,073	461	95,2	444	96,3	88,829	12,699
FU MONTH 24	Asian	442	92,7	423	95,7	90,402	10,345	445	91,9	421	94,6	89,723	11,892
FU MONTH 36	Asian	424	88,9	402	94,8	90,531	10,643	425	87,8	398	93,6	90,013	12,165
BASELINE	Other	52	100,0	52	100,0	90,641	10,077	51	100,0	51	100,0	88,889	13,835
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	81,404	19,431	36	70,6	36	100,0	82,222	19,712
WEEK 13	Other	49	94,2	49	100,0	79,728	20,274	45	88,2	45	100,0	84,148	17,598
WEEK 25	Other	49	94,2	49	100,0	87,755	13,077	42	82,4	41	97,6	88,943	12,257
END OF TREATMENT	Other	52	100,0	47	90,4	89,787	13,467	50	98,0	47	94,0	91,348	9,419
FU MONTH 18	Other	50	96,2	48	96,0	88,993	15,896	44	86,3	39	88,6	91,966	9,933
FU MONTH 24	Other	49	94,2	45	91,8	90,963	15,119	43	84,3	39	90,7	91,795	11,594
FU MONTH 36	Other	49	94,2	44	89,8	90,833	12,329	39	76,5	33	84,6	91,566	10,223
BASELINE	Missing	5	100,0	5	100,0	94,667	5,578	2	100,0	1	50,0	86,667	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	81,333	14,453	2	100,0	2	100,0	96,667	4,714
WEEK 13	Missing	5	100,0	5	100,0	82,667	15,348	2	100,0	2	100,0	96,667	4,714

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	89,333	16,733	2	100,0	2	100,0	100,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	88,333	19,149	2	100,0	1	50,0	93,333	NE
FU MONTH 18	Missing	5	100,0	5	100,0	85,333	17,889	2	100,0	2	100,0	96,667	4,714
FU MONTH 24	Missing	5	100,0	4	80,0	90,000	15,870	2	100,0	2	100,0	96,667	4,714
FU MONTH 36	Missing	5	100,0	5	100,0	85,333	29,212	2	100,0	2	100,0	93,333	9,428

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC01_SG.xls
11AUG2020 15:49

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Role Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1761	97,2	78,734	24,930	1823	100,0	1775	97,4	78,573	25,251
END OF ANTHRACYCLINE	n/a	1432	79,1	1345	93,9	76,642	24,044	1446	79,3	1362	94,2	75,184	25,074
WEEK 13	n/a	1688	93,2	1607	95,2	72,008	26,323	1725	94,6	1636	94,8	71,139	26,742
WEEK 25	n/a	1645	90,8	1585	96,4	79,253	22,718	1688	92,6	1601	94,8	79,763	23,294
END OF TREATMENT	n/a	1794	99,1	1574	87,7	82,063	23,074	1811	99,3	1629	90,0	83,180	22,568
FU MONTH 18	n/a	1663	91,8	1486	89,4	85,206	21,858	1688	92,6	1475	87,4	84,486	21,968
FU MONTH 24	n/a	1633	90,2	1433	87,8	86,857	20,188	1638	89,9	1426	87,1	86,290	20,813
FU MONTH 36	n/a	1571	86,7	1392	88,6	88,147	19,519	1556	85,4	1354	87,0	87,137	20,498
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	79,592	27,484	43	100,0	40	93,0	85,000	25,262
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	79,032	21,929	26	60,5	25	96,2	70,667	30,535
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	73,485	24,725	40	93,0	39	97,5	65,385	29,216
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	77,907	23,492	38	88,4	35	92,1	74,762	24,041
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	85,606	19,880	42	97,7	37	88,1	84,685	24,017
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	91,860	12,793	39	90,7	36	92,3	83,333	26,427

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	90,698	15,128	39	90,7	34	87,2	86,765	19,148
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	90,370	16,472	39	90,7	37	94,9	92,342	12,787
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	251	97,7	83,267	22,632	278	100,0	270	97,1	83,086	23,656
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	79,423	21,642	203	73,0	190	93,6	74,561	26,040
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	234	94,4	75,000	24,573	263	94,6	252	95,8	71,892	26,242
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	80,252	22,550	256	92,1	247	96,5	82,186	22,935
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	226	89,0	84,366	22,198	276	99,3	254	92,0	86,286	20,507
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	86,970	20,874	259	93,2	232	89,6	86,997	19,671
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	88,437	20,750	256	92,1	230	89,8	88,623	19,635
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	90,388	18,175	251	90,3	227	90,4	89,207	20,316
BASELINE	1-3 positive nodes	907	100,0	885	97,6	78,475	25,546	900	100,0	877	97,4	78,069	25,418
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	664	93,1	77,134	23,186	707	78,6	668	94,5	75,150	24,885
WEEK 13	1-3 positive nodes	847	93,4	806	95,2	71,340	26,795	854	94,9	804	94,1	69,942	26,984
WEEK 25	1-3 positive nodes	825	91,0	787	95,4	80,241	22,123	836	92,9	789	94,4	78,559	23,415
END OF TREATMENT	1-3 positive nodes	899	99,1	783	87,1	82,035	22,977	897	99,7	815	90,9	82,413	22,583
FU MONTH 18	1-3 positive nodes	838	92,4	738	88,1	85,050	21,533	852	94,7	745	87,4	84,228	21,463

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	86,813	19,783	830	92,2	726	87,5	85,996	20,618
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	88,156	19,794	794	88,2	669	84,3	86,996	19,966
BASELINE	>= 4 positive nodes	596	100,0	576	96,6	77,083	24,524	602	100,0	588	97,7	76,814	25,462
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	471	95,0	74,735	26,066	510	84,7	479	93,9	75,713	24,689
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	71,574	26,450	568	94,4	541	95,2	72,982	26,346
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	77,402	23,553	558	92,7	530	95,0	80,755	23,135
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	80,806	23,785	596	99,0	523	87,8	82,760	23,313
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	84,055	23,277	538	89,4	462	85,9	83,730	23,426
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	85,835	20,944	513	85,2	436	85,0	85,512	21,819
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	86,768	19,942	472	78,4	421	89,2	85,788	21,835
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1401	97,4	78,932	24,802	1448	100,0	1410	97,4	78,416	25,161
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1343	94,0	76,632	24,052	1444	99,7	1361	94,3	75,178	25,082
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	72,794	26,019	1374	94,9	1302	94,8	71,941	26,373
WEEK 25	Anthracycline containing regimen	1311	91,1	1259	96,0	79,508	22,539	1346	93,0	1276	94,8	80,238	23,380
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1258	88,0	82,035	23,165	1444	99,7	1305	90,4	83,040	22,848

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1185	89,2	85,345	21,811	1340	92,5	1180	88,1	84,336	22,067
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	86,704	20,460	1308	90,3	1137	86,9	86,074	21,039
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1111	88,2	87,909	19,678	1244	85,9	1088	87,5	87,102	20,784
BASELINE	Non-anthracycline containing regimen	372	100,0	360	96,8	77,963	25,443	375	100,0	365	97,3	79,178	25,623
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	83,333	23,570	2	0,5	1	50,0	83,333	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	68,783	27,340	351	93,6	334	95,2	68,014	27,955
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	78,272	23,405	342	91,2	325	95,0	77,897	22,895
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	316	86,6	82,173	22,741	367	97,9	324	88,3	83,745	21,426
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	84,662	22,071	348	92,8	295	84,8	85,085	21,599
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	87,471	19,076	330	88,0	289	87,6	87,140	19,908
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	89,087	18,886	312	83,2	266	85,3	87,281	19,320
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	80,364	23,872	858	100,0	839	97,8	79,321	25,039
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	76,761	23,997	661	77,0	620	93,8	73,844	25,736
WEEK 13	Negative (ER and PgR negative)	815	94,3	775	95,1	72,710	26,435	804	93,7	772	96,0	71,546	26,600
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	79,720	21,828	786	91,6	750	95,4	80,644	22,222
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	81,850	22,768	854	99,5	765	89,6	84,161	21,825
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	719	89,8	86,231	21,049	781	91,0	695	89,0	85,348	21,209
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	87,488	19,798	763	88,9	676	88,6	87,549	20,182
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	678	90,0	88,520	18,602	735	85,7	655	89,1	88,066	20,226
BASELINE	Positive (ER and/or PgR positive)	947	100,0	919	97,0	77,240	25,784	965	100,0	936	97,0	77,902	25,435
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	76,534	24,103	785	81,3	742	94,5	76,303	24,467
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	832	95,3	71,354	26,217	921	95,4	864	93,8	70,775	26,878
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	810	95,7	78,807	23,543	902	93,5	851	94,3	78,986	24,187
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	810	86,4	82,263	23,370	957	99,2	864	90,3	82,311	23,183
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	767	89,0	84,246	22,562	907	94,0	780	86,0	83,718	22,610
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	86,265	20,542	875	90,7	750	85,7	85,156	21,315

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	87,792	20,359	821	85,1	699	85,1	86,266	20,725
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	77,928	27,546	260	100,0	254	97,7	76,247	29,860
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	76,961	24,265	111	42,7	105	94,6	71,905	27,669
WEEK 13	USA/Canada	242	91,3	229	94,6	68,850	28,444	236	90,8	223	94,5	67,862	28,972
WEEK 25	USA/Canada	234	88,3	225	96,2	79,111	24,361	230	88,5	219	95,2	79,148	25,770
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	82,104	25,021	255	98,1	229	89,8	82,242	25,363
FU MONTH 18	USA/Canada	238	89,8	194	81,5	83,505	24,410	231	88,8	181	78,4	85,451	23,243
FU MONTH 24	USA/Canada	231	87,2	188	81,4	86,879	23,237	224	86,2	177	79,0	88,230	20,285
FU MONTH 36	USA/Canada	223	84,2	180	80,7	88,704	21,115	205	78,8	156	76,1	89,850	19,360
BASELINE	Western Europe	827	100,0	789	95,4	76,088	26,671	822	100,0	785	95,5	77,962	26,241
END OF ANTHRACYCLINE	Western Europe	732	88,5	667	91,1	73,238	26,084	728	88,6	663	91,1	72,750	26,956
WEEK 13	Western Europe	764	92,4	700	91,6	68,095	27,657	778	94,6	708	91,0	67,326	28,303
WEEK 25	Western Europe	738	89,2	693	93,9	76,383	24,786	750	91,2	681	90,8	78,292	24,997
END OF TREATMENT	Western Europe	821	99,3	693	84,4	79,101	25,542	817	99,4	704	86,2	81,416	24,472
FU MONTH 18	Western Europe	754	91,2	650	86,2	82,231	24,428	764	92,9	629	82,3	82,273	24,085
FU MONTH 24	Western Europe	739	89,4	614	83,1	84,799	21,950	747	90,9	620	83,0	84,866	22,616
FU MONTH 36	Western Europe	713	86,2	613	86,0	85,971	21,215	712	86,6	599	84,1	85,198	22,372
BASELINE	Asia Pacific	490	100,0	487	99,4	82,033	21,209	512	100,0	508	99,2	80,479	22,133
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	81,150	20,614	397	77,5	390	98,2	78,162	21,369
WEEK 13	Asia Pacific	466	95,1	465	99,8	76,201	23,106	493	96,3	492	99,8	75,474	23,019
WEEK 25	Asia Pacific	461	94,1	461	100,0	82,285	18,926	492	96,1	488	99,2	81,762	19,747

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	84,052	18,959	512	100,0	491	95,9	86,015	18,293
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	88,680	16,620	485	94,7	473	97,5	87,139	18,465
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	88,927	16,673	470	91,8	448	95,3	87,649	18,853
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	89,553	16,920	453	88,5	432	95,4	89,082	17,836
BASELINE	Latin America	43	100,0	43	100,0	88,372	13,380	47	100,0	46	97,9	81,159	22,113
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	87,931	17,760	32	68,1	32	100,0	87,500	17,961
WEEK 13	Latin America	40	93,0	40	100,0	84,167	17,275	44	93,6	44	100,0	75,379	27,015
WEEK 25	Latin America	39	90,7	39	100,0	90,171	13,089	44	93,6	44	100,0	84,848	16,400
END OF TREATMENT	Latin America	42	97,7	38	90,5	93,421	12,580	45	95,7	42	93,3	90,476	17,322
FU MONTH 18	Latin America	41	95,3	37	90,2	93,243	14,938	42	89,4	40	95,2	86,667	18,179
FU MONTH 24	Latin America	40	93,0	36	90,0	95,833	9,237	41	87,2	39	95,1	88,462	15,836
FU MONTH 36	Latin America	38	88,4	34	89,5	97,059	8,675	37	78,7	36	97,3	90,278	13,437
BASELINE	Other	186	100,0	183	98,4	80,237	22,970	182	100,0	182	100,0	78,480	22,490
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	77,938	21,260	178	97,8	172	96,6	77,519	23,330
WEEK 13	Other	176	94,6	173	98,3	77,938	24,241	174	95,6	169	97,1	77,712	23,772
WEEK 25	Other	173	93,0	167	96,5	80,439	21,017	172	94,5	169	98,3	79,389	23,448
END OF TREATMENT	Other	185	99,5	162	87,6	86,317	19,738	182	100,0	163	89,6	81,697	21,692
FU MONTH 18	Other	171	91,9	153	89,5	87,800	19,776	166	91,2	152	91,6	83,662	21,400
FU MONTH 24	Other	169	90,9	154	91,1	87,013	18,888	156	85,7	142	91,0	85,211	20,057
FU MONTH 36	Other	160	86,0	147	91,9	90,476	17,664	149	81,9	131	87,9	85,496	21,819
Protocol version													
BASELINE	Protocol A	1240	100,0	1206	97,3	78,759	25,334	1246	100,0	1209	97,0	79,211	24,922

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	916	93,1	77,111	24,145	988	79,3	928	93,9	74,533	25,152
WEEK 13	Protocol A	1155	93,1	1108	95,9	72,323	26,442	1180	94,7	1112	94,2	70,698	27,140
WEEK 25	Protocol A	1125	90,7	1087	96,6	79,791	22,595	1157	92,9	1092	94,4	79,762	23,111
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	82,945	23,016	1236	99,2	1117	90,4	83,602	22,153
FU MONTH 18	Protocol A	1142	92,1	1026	89,8	85,283	22,667	1156	92,8	1006	87,0	84,510	21,651
FU MONTH 24	Protocol A	1124	90,6	995	88,5	86,918	20,378	1127	90,4	981	87,0	86,544	20,829
FU MONTH 36	Protocol A	1087	87,7	980	90,2	88,827	19,106	1069	85,8	936	87,6	87,838	20,031
BASELINE	Protocol Amendment B	571	100,0	555	97,2	78,679	24,052	577	100,0	566	98,1	77,208	25,911
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	75,641	23,825	458	79,4	434	94,8	76,575	24,876
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	71,309	26,068	545	94,5	524	96,1	72,074	25,878
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	78,079	22,964	531	92,0	509	95,9	79,764	23,705
END OF TREATMENT	Protocol Amendment B	565	98,9	501	88,7	80,173	23,106	575	99,7	512	89,0	82,259	23,442
FU MONTH 18	Protocol Amendment B	521	91,2	460	88,3	85,036	19,958	532	92,2	469	88,2	84,435	22,658
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	86,720	19,770	511	88,6	445	87,1	85,730	20,789
FU MONTH 36	Protocol Amendment B	484	84,8	412	85,1	86,529	20,402	487	84,4	418	85,8	85,566	21,447
Nodal status													
BASELINE	0 positive nodes	308	100,0	300	97,4	82,667	23,482	321	100,0	310	96,6	83,333	23,836
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	79,365	21,632	229	71,3	215	93,9	74,109	26,552
WEEK 13	0 positive nodes	294	95,5	278	94,6	74,760	24,559	303	94,4	291	96,0	71,019	26,698
WEEK 25	0 positive nodes	287	93,2	281	97,9	79,893	22,670	294	91,6	282	95,9	81,265	23,161
END OF TREATMENT	0 positive nodes	305	99,0	270	88,5	84,568	21,807	318	99,1	291	91,5	86,082	20,947
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	87,769	19,843	298	92,8	268	89,9	86,505	20,686

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	88,823	19,895	295	91,9	264	89,5	88,384	19,547
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	90,385	17,861	290	90,3	264	91,0	89,646	19,448
BASELINE	>= 1 positive nodes	1503	100,0	1461	97,2	77,926	25,149	1502	100,0	1465	97,5	77,565	25,435
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	76,138	24,440	1217	81,0	1147	94,2	75,385	24,794
WEEK 13	>= 1 positive nodes	1394	92,7	1329	95,3	71,432	26,650	1422	94,7	1345	94,6	71,165	26,761
WEEK 25	>= 1 positive nodes	1358	90,4	1304	96,0	79,116	22,735	1394	92,8	1319	94,6	79,441	23,319
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1304	87,6	81,544	23,302	1493	99,4	1338	89,6	82,549	22,863
FU MONTH 18	>= 1 positive nodes	1371	91,2	1223	89,2	84,655	22,237	1390	92,5	1207	86,8	84,038	22,227
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	86,438	20,233	1343	89,4	1162	86,5	85,815	21,068
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	87,633	19,852	1266	84,3	1090	86,1	86,529	20,707
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	77,589	25,257	885	100,0	866	97,9	78,137	25,215
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	75,704	24,273	726	82,0	692	95,3	76,782	23,528
WEEK 13	Premenopausal	841	96,3	805	95,7	71,470	26,083	852	96,3	808	94,8	72,215	25,677
WEEK 25	Premenopausal	825	94,5	800	97,0	78,812	23,319	838	94,7	798	95,2	81,495	21,949
END OF TREATMENT	Premenopausal	866	99,2	765	88,3	82,723	22,196	881	99,5	812	92,2	84,483	21,457
FU MONTH 18	Premenopausal	819	93,8	724	88,4	86,303	21,256	835	94,4	740	88,6	86,104	20,321
FU MONTH 24	Premenopausal	803	92,0	705	87,8	87,234	19,907	807	91,2	708	87,7	87,641	18,947

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	88,782	19,565	773	87,3	669	86,5	88,067	19,281
BASELINE	Postmenopausal	933	100,0	903	96,8	79,808	24,534	929	100,0	901	97,0	79,042	25,290
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	665	92,5	77,544	23,807	711	76,5	663	93,2	73,529	26,555
WEEK 13	Postmenopausal	842	90,2	798	94,8	72,473	26,594	864	93,0	820	94,9	70,122	27,703
WEEK 25	Postmenopausal	815	87,4	780	95,7	79,615	22,128	841	90,5	796	94,6	78,120	24,409
END OF TREATMENT	Postmenopausal	923	98,9	805	87,2	81,408	23,878	921	99,1	809	87,8	81,850	23,626
FU MONTH 18	Postmenopausal	839	89,9	759	90,5	84,146	22,400	844	90,9	727	86,1	82,760	23,490
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	86,418	20,494	823	88,6	713	86,6	84,946	22,471
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	87,483	19,503	776	83,5	679	87,5	86,303	21,625
BASELINE	Unknown/Missing	5	100,0	5	100,0	80,000	36,132	9	100,0	8	88,9	72,917	26,633
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	83,333	23,570	9	100,0	7	77,8	73,810	21,207
WEEK 13	Unknown/Missing	5	100,0	4	80,0	87,500	15,957	9	100,0	8	88,9	66,667	30,861
WEEK 25	Unknown/Missing	5	100,0	5	100,0	93,333	9,129	9	100,0	7	77,8	69,048	29,547
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	87,500	25,000	9	100,0	8	88,9	85,417	16,517
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	88,889	19,245	9	100,0	8	88,9	91,667	12,599
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	100,000	0,000	8	88,9	5	62,5	86,667	18,257
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	100,000	0,000	7	77,8	6	85,7	77,778	17,213
Age II													
BASELINE	< 65	1581	100,0	1541	97,5	78,391	25,074	1604	100,0	1567	97,7	78,558	24,960
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	77,012	23,697	1287	80,2	1220	94,8	75,478	24,804
WEEK 13	< 65	1497	94,7	1427	95,3	72,752	25,836	1529	95,3	1452	95,0	71,247	26,489

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1407	96,1	79,531	22,567	1501	93,6	1428	95,1	80,240	22,899
END OF TREATMENT	< 65	1569	99,2	1385	88,3	82,647	22,169	1596	99,5	1446	90,6	83,368	22,352
FU MONTH 18	< 65	1474	93,2	1314	89,1	85,578	21,540	1497	93,3	1318	88,0	84,825	21,519
FU MONTH 24	< 65	1446	91,5	1263	87,3	87,160	20,012	1450	90,4	1270	87,6	86,588	20,359
FU MONTH 36	< 65	1390	87,9	1234	88,8	88,709	19,219	1383	86,2	1206	87,2	87,369	20,207
BASELINE	>= 65	230	100,0	220	95,7	81,136	23,816	219	100,0	208	95,0	78,686	27,409
END OF ANTHRACYCLINE	>= 65	164	71,3	148	90,2	73,649	26,585	159	72,6	142	89,3	72,653	27,241
WEEK 13	>= 65	191	83,0	180	94,2	66,111	29,316	196	89,5	184	93,9	70,290	28,717
WEEK 25	>= 65	181	78,7	178	98,3	77,060	23,828	187	85,4	173	92,5	75,819	26,070
END OF TREATMENT	>= 65	225	97,8	189	84,0	77,778	28,559	215	98,2	183	85,1	81,694	24,216
FU MONTH 18	>= 65	189	82,2	172	91,0	82,364	24,028	191	87,2	157	82,2	81,635	25,331
FU MONTH 24	>= 65	187	81,3	170	90,9	84,608	21,376	188	85,8	156	83,0	83,868	24,128
FU MONTH 36	>= 65	181	78,7	158	87,3	83,755	21,278	173	79,0	148	85,5	85,248	22,715
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	79,570	24,233	24	100,0	24	100,0	81,944	29,454
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	73,529	28,903	17	70,8	16	94,1	72,917	35,421
WEEK 13	Grade 1	31	96,9	30	96,8	61,667	33,946	23	95,8	22	95,7	71,970	33,486
WEEK 25	Grade 1	31	96,9	29	93,5	68,966	32,035	23	95,8	22	95,7	78,030	25,400
END OF TREATMENT	Grade 1	31	96,9	27	87,1	84,568	20,634	24	100,0	22	91,7	81,061	22,000
FU MONTH 18	Grade 1	30	93,8	27	90,0	77,778	33,333	23	95,8	22	95,7	84,091	17,425
FU MONTH 24	Grade 1	28	87,5	27	96,4	81,481	25,459	23	95,8	21	91,3	83,333	20,412
FU MONTH 36	Grade 1	27	84,4	26	96,3	82,051	28,645	22	91,7	20	90,9	85,000	19,421
BASELINE	Grade 2	552	100,0	537	97,3	78,833	24,369	557	100,0	542	97,3	79,213	25,545
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	78,459	23,173	446	80,1	424	95,1	75,825	23,998

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	74,383	25,132	524	94,1	504	96,2	72,288	25,664
WEEK 25	Grade 2	494	89,5	479	97,0	80,654	22,181	515	92,5	493	95,7	80,358	22,595
END OF TREATMENT	Grade 2	548	99,3	485	88,5	83,333	22,828	553	99,3	496	89,7	82,829	22,876
FU MONTH 18	Grade 2	507	91,8	457	90,1	86,652	20,985	517	92,8	448	86,7	85,045	20,636
FU MONTH 24	Grade 2	501	90,8	449	89,6	87,751	19,850	500	89,8	431	86,2	86,002	20,554
FU MONTH 36	Grade 2	487	88,2	438	89,9	89,878	17,330	476	85,5	414	87,0	88,084	19,689
BASELINE	Grade 3	1161	100,0	1130	97,3	78,437	25,256	1173	100,0	1141	97,3	78,148	25,017
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	75,448	24,366	919	78,3	860	93,6	74,593	25,687
WEEK 13	Grade 3	1088	93,7	1030	94,7	71,117	26,623	1114	95,0	1050	94,3	70,603	27,159
WEEK 25	Grade 3	1059	91,2	1019	96,2	78,754	22,571	1087	92,7	1024	94,2	79,492	23,729
END OF TREATMENT	Grade 3	1150	99,1	1001	87,0	81,269	23,337	1165	99,3	1051	90,2	83,428	22,490
FU MONTH 18	Grade 3	1067	91,9	948	88,8	84,705	21,796	1085	92,5	946	87,2	84,355	22,579
FU MONTH 24	Grade 3	1046	90,1	903	86,3	86,397	20,219	1053	89,8	918	87,2	86,420	20,962
FU MONTH 36	Grade 3	1002	86,3	876	87,4	87,272	20,111	999	85,2	868	86,9	86,886	20,763
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	82,804	24,313	69	100,0	68	98,6	79,412	25,613
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	82,986	22,673	64	92,8	62	96,9	79,570	20,113
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	73,224	24,773	64	92,8	60	93,8	70,556	25,923
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	81,609	23,088	63	91,3	62	98,4	80,108	21,090
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	83,880	21,510	69	100,0	60	87,0	82,500	22,005
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	85,494	22,674	63	91,3	59	93,7	82,486	23,656

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	89,815	19,268	62	89,9	56	90,3	87,500	20,901
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	91,346	20,209	59	85,5	52	88,1	84,615	22,830
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	705	96,8	81,182	24,644	715	100,0	686	95,9	81,147	25,537
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	547	92,4	76,417	24,154	572	80,0	522	91,3	74,553	26,550
WEEK 13	Breast conserving surgery	677	93,0	638	94,2	70,219	28,241	673	94,1	631	93,8	67,538	27,032
WEEK 25	Breast conserving surgery	665	91,3	639	96,1	77,517	24,717	654	91,5	613	93,7	79,038	24,040
END OF TREATMENT	Breast conserving surgery	722	99,2	625	86,6	80,907	24,109	711	99,4	621	87,3	82,421	23,591
FU MONTH 18	Breast conserving surgery	678	93,1	596	87,9	84,116	22,668	659	92,2	560	85,0	84,018	22,492
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	86,227	21,066	644	90,1	555	86,2	86,577	20,681
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	87,989	20,359	616	86,2	537	87,2	87,461	20,209
BASELINE	Mastectomy	1083	100,0	1056	97,5	77,099	24,997	1107	100,0	1088	98,3	76,945	24,956
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	76,796	23,982	873	78,9	839	96,1	75,566	24,132
WEEK 13	Mastectomy	1011	93,4	969	95,8	73,185	24,924	1051	94,9	1004	95,5	73,406	26,333
WEEK 25	Mastectomy	980	90,5	946	96,5	80,426	21,195	1033	93,3	987	95,5	80,226	22,828
END OF TREATMENT	Mastectomy	1072	99,0	949	88,5	82,824	22,346	1099	99,3	1007	91,6	83,697	21,866
FU MONTH 18	Mastectomy	985	91,0	890	90,4	85,936	21,280	1028	92,9	914	88,9	84,792	21,653
FU MONTH 24	Mastectomy	967	89,3	857	88,6	87,281	19,576	993	89,7	870	87,6	86,111	20,918

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	830	90,2	88,253	18,941	939	84,8	817	87,0	86,924	20,695
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	644	97,6	80,305	24,800	665	100,0	639	96,1	80,203	24,772
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	77,019	23,246	523	78,6	493	94,3	73,529	25,050
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	71,412	26,386	631	94,9	606	96,0	69,829	26,376
WEEK 25	0 - < 2 cm	608	92,1	583	95,9	79,989	22,210	617	92,8	588	95,3	79,705	23,126
END OF TREATMENT	0 - < 2 cm	655	99,2	578	88,2	82,151	23,469	661	99,4	599	90,6	83,500	22,000
FU MONTH 18	0 - < 2 cm	617	93,5	546	88,5	85,958	21,375	624	93,8	561	89,9	84,254	22,242
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	87,890	18,937	606	91,1	530	87,5	87,767	19,274
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	89,079	18,543	580	87,2	507	87,4	88,560	19,478
BASELINE	>= 2 - < 5 cm	1009	100,0	978	96,9	78,289	24,749	991	100,0	971	98,0	77,841	25,623
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	754	94,6	76,459	24,285	789	79,6	743	94,2	75,684	25,482
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	72,284	26,298	940	94,9	888	94,5	70,908	27,027
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	78,902	23,136	919	92,7	865	94,1	79,422	23,402
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	82,604	22,615	985	99,4	876	88,9	83,124	22,331

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	830	89,9	85,321	21,560	914	92,2	783	85,7	84,163	22,004
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	86,263	20,941	889	89,7	777	87,4	85,285	21,773
FU MONTH 36	>= 2 - < 5 cm	857	84,9	763	89,0	87,615	20,239	839	84,7	729	86,9	86,237	21,083
BASELINE	>= 5 cm	139	100,0	137	98,6	74,209	26,350	165	100,0	163	98,8	76,789	24,737
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	75,873	26,147	132	80,0	124	93,9	78,898	22,402
WEEK 13	>= 5 cm	130	93,5	125	96,2	72,667	26,216	152	92,1	140	92,1	78,095	25,687
WEEK 25	>= 5 cm	124	89,2	119	96,0	78,151	22,313	150	90,9	146	97,3	82,192	23,132
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	78,133	24,172	163	98,8	152	93,3	82,237	26,066
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	80,685	25,916	148	89,7	129	87,2	87,726	20,039
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	85,886	20,744	141	85,5	117	83,0	86,467	20,638
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	87,459	18,768	135	81,8	116	85,9	86,638	20,992
BASELINE	Missing	3	100,0	2	66,7	100,000	0,000	2	100,0	2	100,0	58,333	11,785
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	66,667	0,000
WEEK 13	Missing	3	100,0	3	100,0	77,778	38,490	2	100,0	2	100,0	83,333	23,570
WEEK 25	Missing	3	100,0	3	100,0	83,333	16,667	2	100,0	2	100,0	66,667	47,140
END OF TREATMENT	Missing	3	100,0	3	100,0	72,222	25,459	2	100,0	2	100,0	83,333	23,570
FU MONTH 18	Missing	3	100,0	3	100,0	77,778	25,459	2	100,0	2	100,0	66,667	47,140
FU MONTH 24	Missing	3	100,0	3	100,0	94,444	9,623	2	100,0	2	100,0	75,000	35,355
FU MONTH 36	Missing	3	100,0	3	100,0	83,333	28,868	2	100,0	2	100,0	83,333	23,570
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1320	98,0	78,952	24,924	1350	100,0	1312	97,2	79,065	25,363
END OF ANTHRACYCLINE	Yes	1103	81,9	1046	94,8	76,514	24,000	1104	81,8	1043	94,5	75,072	25,033
WEEK 13	Yes	1308	97,1	1245	95,2	71,861	26,635	1324	98,1	1248	94,3	70,980	26,554
WEEK 25	Yes	1277	94,8	1227	96,1	78,484	23,120	1302	96,4	1228	94,3	80,076	23,383

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1213	90,1	81,506	23,387	1350	100,0	1236	91,6	83,333	22,655
FU MONTH 18	Yes	1291	95,8	1146	88,8	84,671	22,380	1298	96,1	1131	87,1	84,380	22,342
FU MONTH 24	Yes	1266	94,0	1110	87,7	86,291	20,744	1260	93,3	1091	86,6	86,053	21,280
FU MONTH 36	Yes	1219	90,5	1062	87,1	87,994	19,737	1195	88,5	1038	86,9	86,978	20,943
BASELINE	No	464	100,0	441	95,0	78,080	24,964	473	100,0	463	97,9	77,178	24,908
END OF ANTHRACYCLINE	No	329	70,9	299	90,9	77,090	24,234	342	72,3	319	93,3	75,549	25,242
WEEK 13	No	380	81,9	362	95,3	72,514	25,248	401	84,8	388	96,8	71,649	27,365
WEEK 25	No	368	79,3	358	97,3	81,890	21,102	386	81,6	373	96,6	78,731	23,002
END OF TREATMENT	No	447	96,3	361	80,8	83,934	21,917	461	97,5	393	85,2	82,697	22,310
FU MONTH 18	No	372	80,2	340	91,4	87,010	19,924	390	82,5	344	88,2	84,835	20,722
FU MONTH 24	No	367	79,1	323	88,0	88,803	18,039	378	79,9	335	88,6	87,065	19,221
FU MONTH 36	No	352	75,9	330	93,8	88,636	18,822	361	76,3	316	87,5	87,658	18,985
Race													
BASELINE	White	1252	100,0	1206	96,3	77,211	26,474	1255	100,0	1214	96,7	77,787	26,130
END OF ANTHRACYCLINE	White	1010	80,7	932	92,3	75,036	24,990	1018	81,1	941	92,4	73,645	26,110
WEEK 13	White	1158	92,5	1086	93,8	70,350	27,412	1183	94,3	1096	92,6	69,206	28,032
WEEK 25	White	1120	89,5	1063	94,9	77,955	24,239	1150	91,6	1071	93,1	78,852	24,912
END OF TREATMENT	White	1238	98,9	1049	84,7	81,141	24,754	1244	99,1	1089	87,5	81,696	24,288
FU MONTH 18	White	1138	90,9	982	86,3	84,063	23,565	1152	91,8	966	83,9	83,161	23,606
FU MONTH 24	White	1115	89,1	943	84,6	85,755	21,701	1120	89,2	941	84,0	85,264	22,003
FU MONTH 36	White	1071	85,5	923	86,2	87,360	20,837	1064	84,8	901	84,7	85,979	21,775
BASELINE	Black	25	100,0	24	96,0	77,778	24,409	31	100,0	30	96,8	65,000	35,920
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	72,222	20,412	15	48,4	15	100,0	66,667	31,497
WEEK 13	Black	21	84,0	17	81,0	67,647	22,415	29	93,5	28	96,6	64,286	29,991

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	76,316	23,118	29	93,5	28	96,6	73,214	22,379
END OF TREATMENT	Black	24	96,0	22	91,7	81,061	22,000	31	100,0	28	90,3	79,167	25,103
FU MONTH 18	Black	23	92,0	17	73,9	74,510	22,911	29	93,5	24	82,8	72,917	24,481
FU MONTH 24	Black	22	88,0	18	81,8	87,963	20,457	28	90,3	23	82,1	84,058	22,178
FU MONTH 36	Black	22	88,0	18	81,8	87,037	16,721	26	83,9	20	76,9	84,167	25,635
BASELINE	Asian	477	100,0	475	99,6	82,000	21,034	484	100,0	480	99,2	81,007	21,802
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	80,563	20,935	375	77,5	368	98,1	78,850	21,174
WEEK 13	Asian	455	95,4	450	98,9	75,852	23,244	466	96,3	465	99,8	75,484	22,450
WEEK 25	Asian	450	94,3	449	99,8	81,849	18,708	465	96,1	459	98,7	81,736	19,451
END OF TREATMENT	Asian	475	99,6	452	95,2	83,518	19,078	484	100,0	464	95,9	86,207	17,869
FU MONTH 18	Asian	447	93,7	434	97,1	88,095	16,658	461	95,2	444	96,3	87,500	17,905
FU MONTH 24	Asian	442	92,7	423	95,7	88,652	16,783	445	91,9	421	94,6	88,282	17,963
FU MONTH 36	Asian	424	88,9	402	94,8	89,469	16,384	425	87,8	398	93,6	89,573	17,168
BASELINE	Other	52	100,0	52	100,0	85,577	15,839	51	100,0	50	98,0	82,000	23,771
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	79,825	25,749	36	70,6	36	100,0	80,093	27,261
WEEK 13	Other	49	94,2	49	100,0	75,510	25,708	45	88,2	45	100,0	76,296	27,636
WEEK 25	Other	49	94,2	49	100,0	84,694	19,790	42	82,4	41	97,6	84,959	16,999
END OF TREATMENT	Other	52	100,0	47	90,4	89,007	17,123	50	98,0	47	94,0	89,716	16,866
FU MONTH 18	Other	50	96,2	48	96,0	87,500	21,880	44	86,3	39	88,6	89,744	14,109
FU MONTH 24	Other	49	94,2	45	91,8	92,593	14,458	43	84,3	39	90,7	90,171	17,819
FU MONTH 36	Other	49	94,2	44	89,8	92,803	18,115	39	76,5	33	84,6	90,404	15,607
BASELINE	Missing	5	100,0	4	80,0	66,667	27,217	2	100,0	1	50,0	100,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	76,667	19,003	2	100,0	2	100,0	100,000	0,000
WEEK 13	Missing	5	100,0	5	100,0	66,667	33,333	2	100,0	2	100,0	100,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	80,000	21,731	2	100,0	2	100,0	100,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	83,333	33,333	2	100,0	1	50,0	100,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	73,333	38,370	2	100,0	2	100,0	91,667	11,785
FU MONTH 24	Missing	5	100,0	4	80,0	87,500	15,957	2	100,0	2	100,0	100,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	90,000	14,907	2	100,0	2	100,0	100,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC02_SG.xls
11AUG2020 15:51

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Emotional Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1760	97,2	73,018	22,343	1823	100,0	1778	97,5	71,691	22,951
END OF ANTHRACYCLINE	n/a	1432	79,1	1342	93,7	75,439	21,960	1446	79,3	1360	94,1	73,358	21,877
WEEK 13	n/a	1688	93,2	1607	95,2	76,319	22,458	1725	94,6	1639	95,0	74,439	22,860
WEEK 25	n/a	1645	90,8	1581	96,1	78,519	21,245	1688	92,6	1601	94,8	77,871	21,379
END OF TREATMENT	n/a	1794	99,1	1571	87,6	79,726	20,965	1811	99,3	1626	89,8	78,082	22,138
FU MONTH 18	n/a	1663	91,8	1482	89,1	80,387	20,912	1688	92,6	1471	87,1	78,526	21,445
FU MONTH 24	n/a	1633	90,2	1433	87,8	81,007	20,840	1638	89,9	1424	86,9	79,662	21,452
FU MONTH 36	n/a	1571	86,7	1391	88,5	81,288	21,478	1556	85,4	1351	86,8	79,410	21,855
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	76,417	23,963	43	100,0	40	93,0	72,778	23,463
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	72,760	25,634	26	60,5	25	96,2	70,667	21,004
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	76,010	23,715	40	93,0	39	97,5	72,650	24,296
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	74,806	22,366	38	88,4	35	92,1	74,921	24,895
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	78,409	19,028	42	97,7	37	88,1	75,375	22,549
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	80,879	19,597	39	90,7	36	92,3	78,086	20,996

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	82,946	19,898	39	90,7	34	87,2	78,431	18,540
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	84,938	18,525	39	90,7	37	94,9	82,282	18,603
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	75,000	20,937	278	100,0	271	97,5	72,530	22,746
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	76,717	21,315	203	73,0	191	94,1	73,357	22,624
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	79,764	19,819	263	94,6	253	96,2	73,430	23,511
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	80,696	20,233	256	92,1	246	96,1	79,178	19,325
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	81,155	21,217	276	99,3	255	92,4	77,386	22,897
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	82,390	21,048	259	93,2	232	89,6	78,424	20,567
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	83,519	20,152	256	92,1	229	89,5	79,646	20,522
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	85,039	20,528	251	90,3	227	90,4	80,078	21,991
BASELINE	1-3 positive nodes	907	100,0	884	97,5	72,360	22,612	900	100,0	878	97,6	71,273	22,507
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	662	92,8	74,992	22,011	707	78,6	666	94,2	73,624	21,519
WEEK 13	1-3 positive nodes	847	93,4	806	95,2	75,800	22,608	854	94,9	806	94,4	74,959	21,717
WEEK 25	1-3 positive nodes	825	91,0	785	95,2	78,011	21,899	836	92,9	790	94,5	78,003	21,723
END OF TREATMENT	1-3 positive nodes	899	99,1	780	86,8	79,466	20,664	897	99,7	811	90,4	78,716	21,235
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	80,314	20,782	852	94,7	742	87,1	78,684	21,110

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	80,243	21,093	830	92,2	726	87,5	79,721	20,735
FU MONTH 36	1-3 positive nodes	804	88,6	704	87,6	80,224	21,663	794	88,2	668	84,1	80,273	20,544
BASELINE	>= 4 positive nodes	596	100,0	575	96,5	72,870	22,366	602	100,0	589	97,8	71,854	23,697
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	471	95,0	75,761	21,911	510	84,7	478	93,7	73,129	22,166
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	75,596	23,147	568	94,4	541	95,2	74,266	24,112
WEEK 25	>= 4 positive nodes	533	89,4	515	96,6	78,598	20,556	558	92,7	530	95,0	77,264	21,543
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	79,605	21,483	596	99,0	523	87,8	77,629	23,111
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	79,553	21,163	538	89,4	461	85,7	78,356	22,488
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	80,893	20,796	513	85,2	435	84,8	79,668	23,306
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	80,770	21,748	472	78,4	419	88,8	77,420	23,911
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1401	97,4	72,575	22,500	1448	100,0	1413	97,6	72,053	22,875
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1340	93,8	75,402	21,956	1444	99,7	1359	94,1	73,363	21,884
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	76,316	22,349	1374	94,9	1304	94,9	75,030	22,810
WEEK 25	Anthracycline containing regimen	1311	91,1	1255	95,7	78,544	21,122	1346	93,0	1276	94,8	77,486	21,459
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	79,481	21,010	1444	99,7	1301	90,1	77,650	22,600

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1183	89,0	80,455	20,553	1340	92,5	1175	87,7	78,421	21,618
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	80,500	21,031	1308	90,3	1135	86,8	79,687	21,900
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1110	88,2	80,931	21,636	1244	85,9	1085	87,2	79,073	22,144
BASELINE	Non-anthracycline containing regimen	372	100,0	359	96,5	74,745	21,666	375	100,0	365	97,3	70,289	23,220
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	100,000	0,000	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	76,332	22,933	351	93,6	335	95,4	72,139	22,940
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	78,425	21,742	342	91,2	325	95,0	79,385	21,026
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	80,705	20,788	367	97,9	325	88,6	79,812	20,120
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	80,119	22,313	348	92,8	296	85,1	78,941	20,774
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	83,042	19,964	330	88,0	289	87,6	79,566	19,628
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	82,701	20,820	312	83,2	266	85,3	80,785	20,618
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	73,661	22,655	858	100,0	840	97,9	71,984	23,168
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	637	94,8	74,699	22,184	661	77,0	620	93,8	72,688	22,604
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	77,083	21,956	804	93,7	773	96,1	74,536	23,154
WEEK 25	Negative (ER and PgR negative)	799	92,5	772	96,6	79,174	20,911	786	91,6	750	95,4	78,837	20,350
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	79,923	20,571	854	99,5	764	89,5	78,621	21,304
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	716	89,4	81,277	20,738	781	91,0	693	88,7	78,756	21,132
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	81,780	20,286	763	88,9	675	88,5	80,091	20,778
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	82,381	20,217	735	85,7	654	89,0	80,020	21,183
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	72,428	22,049	965	100,0	938	97,2	71,429	22,765
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	705	92,8	76,107	21,750	785	81,3	740	94,3	73,919	21,247
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	75,605	22,906	921	95,4	866	94,0	74,352	22,606
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	809	95,6	77,895	21,553	902	93,5	851	94,3	77,020	22,224
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	807	86,0	79,540	21,342	957	99,2	862	90,1	77,604	22,852
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	79,555	21,054	907	94,0	778	85,8	78,320	21,731
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	80,281	21,336	875	90,7	749	85,6	79,276	22,048

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	80,252	22,574	821	85,1	697	84,9	78,838	22,468
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	75,538	21,424	260	100,0	255	98,1	70,458	24,897
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	79,847	18,350	111	42,7	104	93,7	72,009	24,332
WEEK 13	USA/Canada	242	91,3	229	94,6	75,255	22,394	236	90,8	224	94,9	70,982	24,624
WEEK 25	USA/Canada	234	88,3	225	96,2	78,074	20,811	230	88,5	219	95,2	77,270	24,263
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	79,424	20,323	255	98,1	229	89,8	78,918	23,694
FU MONTH 18	USA/Canada	238	89,8	194	81,5	78,121	23,039	231	88,8	179	77,5	78,057	24,467
FU MONTH 24	USA/Canada	231	87,2	188	81,4	79,048	22,204	224	86,2	177	79,0	79,755	23,416
FU MONTH 36	USA/Canada	223	84,2	180	80,7	79,753	24,074	205	78,8	156	76,1	79,274	24,960
BASELINE	Western Europe	827	100,0	788	95,3	68,824	24,050	822	100,0	787	95,7	68,410	24,038
END OF ANTHRACYCLINE	Western Europe	732	88,5	664	90,7	72,883	23,497	728	88,6	662	90,9	71,375	22,665
WEEK 13	Western Europe	764	92,4	700	91,6	73,841	24,192	778	94,6	710	91,3	71,933	24,637
WEEK 25	Western Europe	738	89,2	691	93,6	75,269	23,717	750	91,2	680	90,7	75,270	22,929
END OF TREATMENT	Western Europe	821	99,3	691	84,2	76,467	23,472	817	99,4	702	85,9	74,367	24,333
FU MONTH 18	Western Europe	754	91,2	647	85,8	76,962	22,763	764	92,9	630	82,5	75,282	22,890
FU MONTH 24	Western Europe	739	89,4	614	83,1	77,597	22,858	747	90,9	618	82,7	77,041	23,020
FU MONTH 36	Western Europe	713	86,2	613	86,0	78,113	23,429	712	86,6	596	83,7	76,352	23,438
BASELINE	Asia Pacific	490	100,0	487	99,4	78,417	19,075	512	100,0	508	99,2	77,483	19,824
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	78,847	20,116	397	77,5	390	98,2	77,991	20,438
WEEK 13	Asia Pacific	466	95,1	465	99,8	80,550	19,030	493	96,3	492	99,8	79,968	18,423
WEEK 25	Asia Pacific	461	94,1	460	99,8	83,671	17,236	492	96,1	488	99,2	83,026	16,935

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	84,339	17,034	512	100,0	490	95,7	83,322	17,509
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	85,908	16,518	485	94,7	470	96,9	83,522	17,901
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	86,772	15,498	470	91,8	448	95,3	84,201	17,424
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	86,064	16,515	453	88,5	432	95,4	84,156	17,488
BASELINE	Latin America	43	100,0	43	100,0	79,587	18,770	47	100,0	46	97,9	69,807	17,633
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	77,778	22,420	32	68,1	32	100,0	70,486	22,860
WEEK 13	Latin America	40	93,0	40	100,0	78,889	19,620	44	93,6	44	100,0	71,212	19,951
WEEK 25	Latin America	39	90,7	39	100,0	83,761	13,691	44	93,6	44	100,0	75,758	13,613
END OF TREATMENT	Latin America	42	97,7	38	90,5	85,965	13,592	45	95,7	42	93,3	77,778	18,200
FU MONTH 18	Latin America	41	95,3	37	90,2	87,087	15,161	42	89,4	40	95,2	77,222	18,988
FU MONTH 24	Latin America	40	93,0	36	90,0	89,506	14,290	41	87,2	39	95,1	78,348	17,651
FU MONTH 36	Latin America	38	88,4	34	89,5	89,869	15,801	37	78,7	36	97,3	80,556	13,380
BASELINE	Other	186	100,0	184	98,9	71,618	21,092	182	100,0	182	100,0	71,917	21,684
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	74,888	20,285	178	97,8	172	96,6	71,835	18,631
WEEK 13	Other	176	94,6	173	98,3	75,787	22,913	174	95,6	169	97,1	74,293	22,360
WEEK 25	Other	173	93,0	166	96,0	77,142	19,624	172	94,5	170	98,8	74,804	21,607
END OF TREATMENT	Other	185	99,5	162	87,6	79,355	19,497	182	100,0	163	89,6	77,232	20,241
FU MONTH 18	Other	171	91,9	153	89,5	79,847	19,095	166	91,2	152	91,6	77,412	19,411
FU MONTH 24	Other	169	90,9	154	91,1	78,499	21,472	156	85,7	142	91,0	76,995	22,169
FU MONTH 36	Other	160	86,0	147	91,9	80,877	20,471	149	81,9	131	87,9	77,523	22,790
Protocol version													
BASELINE	Protocol A	1240	100,0	1204	97,1	72,794	22,720	1246	100,0	1211	97,2	71,543	22,880

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	915	93,0	76,011	21,944	988	79,3	926	93,7	72,528	22,025
WEEK 13	Protocol A	1155	93,1	1108	95,9	76,830	22,440	1180	94,7	1114	94,4	73,763	23,451
WEEK 25	Protocol A	1125	90,7	1083	96,3	79,127	21,191	1157	92,9	1092	94,4	77,671	21,532
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	80,470	20,882	1236	99,2	1114	90,1	77,638	22,166
FU MONTH 18	Protocol A	1142	92,1	1023	89,6	80,748	20,902	1156	92,8	1002	86,7	78,088	21,567
FU MONTH 24	Protocol A	1124	90,6	995	88,5	81,508	20,866	1127	90,4	979	86,9	78,986	21,432
FU MONTH 36	Protocol A	1087	87,7	980	90,2	81,786	21,287	1069	85,8	934	87,4	79,532	21,692
BASELINE	Protocol Amendment B	571	100,0	556	97,4	73,501	21,519	577	100,0	567	98,3	72,007	23,118
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	427	95,3	74,213	21,970	458	79,4	434	94,8	75,128	21,476
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	75,184	22,478	545	94,5	525	96,3	75,873	21,503
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	77,198	21,322	531	92,0	509	95,9	78,302	21,062
END OF TREATMENT	Protocol Amendment B	565	98,9	498	88,1	78,124	21,073	575	99,7	512	89,0	79,047	22,067
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	79,581	20,937	532	92,2	469	88,2	79,460	21,175
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	79,871	20,761	511	88,6	445	87,1	81,149	21,446
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	80,103	21,908	487	84,4	417	85,6	79,137	22,241
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	75,231	21,422	321	100,0	311	96,9	72,562	22,801
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	76,130	21,986	229	71,3	216	94,3	73,045	22,413
WEEK 13	0 positive nodes	294	95,5	279	94,9	79,172	20,481	303	94,4	292	96,4	73,326	23,576
WEEK 25	0 positive nodes	287	93,2	281	97,9	79,794	20,641	294	91,6	281	95,6	78,648	20,100
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	80,709	20,868	318	99,1	292	91,8	77,131	22,825
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	82,141	20,787	298	92,8	268	89,9	78,379	20,585

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	83,422	20,071	295	91,9	263	89,2	79,489	20,247
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	85,021	20,161	290	90,3	264	91,0	80,387	21,530
BASELINE	>= 1 positive nodes	1503	100,0	1459	97,1	72,561	22,509	1502	100,0	1467	97,7	71,506	22,986
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1133	93,7	75,311	21,963	1217	81,0	1144	94,0	73,417	21,784
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	75,720	22,813	1422	94,7	1347	94,7	74,680	22,703
WEEK 25	>= 1 positive nodes	1358	90,4	1300	95,7	78,244	21,371	1394	92,8	1320	94,7	77,706	21,645
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1300	87,3	79,521	20,987	1493	99,4	1334	89,4	78,290	21,987
FU MONTH 18	>= 1 positive nodes	1371	91,2	1221	89,1	80,012	20,929	1390	92,5	1203	86,5	78,558	21,640
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	80,492	20,973	1343	89,4	1161	86,4	79,701	21,724
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	80,430	21,687	1266	84,3	1087	85,9	79,173	21,937
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	852	97,6	72,066	22,368	885	100,0	868	98,1	72,184	22,720
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	75,148	22,157	726	82,0	693	95,5	74,186	21,060
WEEK 13	Premenopausal	841	96,3	806	95,8	74,800	22,646	852	96,3	809	95,0	74,550	23,055
WEEK 25	Premenopausal	825	94,5	797	96,6	76,913	21,367	838	94,7	800	95,5	76,875	21,887
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	79,016	20,727	881	99,5	810	91,9	78,224	22,191
FU MONTH 18	Premenopausal	819	93,8	724	88,4	79,619	21,271	835	94,4	736	88,1	78,382	21,544
FU MONTH 24	Premenopausal	803	92,0	705	87,8	79,913	21,407	807	91,2	707	87,6	79,852	21,377

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	80,291	22,036	773	87,3	668	86,4	79,541	21,705
BASELINE	Postmenopausal	933	100,0	903	96,8	73,902	22,312	929	100,0	902	97,1	71,261	23,153
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	661	91,9	75,702	21,822	711	76,5	660	92,8	72,593	22,641
WEEK 13	Postmenopausal	842	90,2	797	94,7	77,806	22,206	864	93,0	822	95,1	74,351	22,738
WEEK 25	Postmenopausal	815	87,4	779	95,6	80,081	21,031	841	90,5	794	94,4	78,918	20,845
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	80,341	21,192	921	99,1	808	87,7	77,963	22,108
FU MONTH 18	Postmenopausal	839	89,9	755	90,0	81,118	20,574	844	90,9	727	86,1	78,725	21,351
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	82,029	20,267	823	88,6	712	86,5	79,533	21,534
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	82,183	20,944	776	83,5	677	87,2	79,378	21,796
BASELINE	Unknown/Missing	5	100,0	5	100,0	75,556	21,373	9	100,0	8	88,9	66,667	26,561
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	80,000	14,487	9	100,0	7	77,8	63,492	26,227
WEEK 13	Unknown/Missing	5	100,0	4	80,0	86,111	13,981	9	100,0	8	88,9	72,222	16,798
WEEK 25	Unknown/Missing	5	100,0	5	100,0	91,111	14,487	9	100,0	7	77,8	73,016	19,092
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	91,667	16,667	9	100,0	8	88,9	75,694	22,210
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	81,481	16,973	9	100,0	8	88,9	73,611	22,954
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	88,889	12,830	8	88,9	5	62,5	71,111	23,040
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	88,889	15,713	7	77,8	6	85,7	68,519	41,821
Age II													
BASELINE	< 65	1581	100,0	1541	97,5	72,932	22,350	1604	100,0	1570	97,9	71,854	22,873
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	75,564	21,905	1287	80,2	1220	94,8	73,406	21,826
WEEK 13	< 65	1497	94,7	1427	95,3	76,474	22,239	1529	95,3	1455	95,2	74,028	22,961

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	78,213	21,148	1501	93,6	1428	95,1	77,494	21,624
END OF TREATMENT	< 65	1569	99,2	1383	88,1	79,847	20,827	1596	99,5	1443	90,4	77,828	22,279
FU MONTH 18	< 65	1474	93,2	1311	88,9	80,363	21,001	1497	93,3	1315	87,8	78,348	21,661
FU MONTH 24	< 65	1446	91,5	1263	87,3	80,712	21,102	1450	90,4	1268	87,4	79,587	21,483
FU MONTH 36	< 65	1390	87,9	1233	88,7	81,171	21,602	1383	86,2	1202	86,9	79,382	21,798
BASELINE	>= 65	230	100,0	219	95,2	73,617	22,340	219	100,0	208	95,0	70,459	23,555
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	74,406	22,465	159	72,6	140	88,1	72,937	22,390
WEEK 13	>= 65	191	83,0	180	94,2	75,093	24,152	196	89,5	184	93,9	77,687	21,828
WEEK 25	>= 65	181	78,7	178	98,3	80,930	21,905	187	85,4	173	92,5	80,989	19,011
END OF TREATMENT	>= 65	225	97,8	188	83,6	78,842	21,987	215	98,2	183	85,1	80,085	20,935
FU MONTH 18	>= 65	189	82,2	171	90,5	80,572	20,277	191	87,2	156	81,7	80,021	19,530
FU MONTH 24	>= 65	187	81,3	170	90,9	83,203	18,696	188	85,8	156	83,0	80,271	21,254
FU MONTH 36	>= 65	181	78,7	158	87,3	82,208	20,528	173	79,0	149	86,1	79,642	22,387
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	71,326	29,505	24	100,0	24	100,0	80,556	21,044
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	83,007	22,946	17	70,8	16	94,1	75,000	28,255
WEEK 13	Grade 1	31	96,9	30	96,8	70,000	31,039	23	95,8	22	95,7	78,788	24,224
WEEK 25	Grade 1	31	96,9	28	90,3	73,413	27,441	23	95,8	22	95,7	79,798	24,158
END OF TREATMENT	Grade 1	31	96,9	27	87,1	79,630	21,295	24	100,0	22	91,7	78,788	19,370
FU MONTH 18	Grade 1	30	93,8	27	90,0	82,716	24,909	23	95,8	22	95,7	78,283	23,377
FU MONTH 24	Grade 1	28	87,5	27	96,4	81,481	20,672	23	95,8	21	91,3	82,540	23,193
FU MONTH 36	Grade 1	27	84,4	26	96,3	79,060	25,978	22	91,7	20	90,9	78,333	25,611
BASELINE	Grade 2	552	100,0	536	97,1	73,818	21,087	557	100,0	543	97,5	72,212	22,241
END OF ANTHRACYCLINE	Grade 2	445	80,6	422	94,8	76,422	21,388	446	80,1	424	95,1	73,703	22,348

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	77,412	21,896	524	94,1	504	96,2	75,419	22,422
WEEK 25	Grade 2	494	89,5	479	97,0	80,097	20,563	515	92,5	492	95,5	78,444	20,926
END OF TREATMENT	Grade 2	548	99,3	485	88,5	81,214	21,258	553	99,3	495	89,5	78,171	22,638
FU MONTH 18	Grade 2	507	91,8	456	89,9	81,530	19,068	517	92,8	447	86,5	78,983	21,516
FU MONTH 24	Grade 2	501	90,8	449	89,6	82,059	20,269	500	89,8	431	86,2	79,814	21,874
FU MONTH 36	Grade 2	487	88,2	437	89,7	83,677	20,283	476	85,5	414	87,0	80,596	21,913
BASELINE	Grade 3	1161	100,0	1130	97,3	72,596	22,794	1173	100,0	1143	97,4	71,177	23,257
END OF ANTHRACYCLINE	Grade 3	918	79,1	855	93,1	74,659	22,167	919	78,3	858	93,4	72,902	21,661
WEEK 13	Grade 3	1088	93,7	1030	94,7	75,814	22,307	1114	95,0	1053	94,5	73,615	23,223
WEEK 25	Grade 3	1059	91,2	1016	95,9	77,783	21,266	1087	92,7	1025	94,3	77,322	21,731
END OF TREATMENT	Grade 3	1150	99,1	998	86,8	78,980	20,749	1165	99,3	1049	90,0	77,894	22,037
FU MONTH 18	Grade 3	1067	91,9	945	88,6	79,706	21,283	1085	92,5	944	87,0	78,425	21,220
FU MONTH 24	Grade 3	1046	90,1	903	86,3	80,269	21,087	1053	89,8	916	87,0	79,458	21,283
FU MONTH 36	Grade 3	1002	86,3	876	87,4	80,055	21,773	999	85,2	866	86,7	78,695	21,962
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	74,603	20,780	69	100,0	68	98,6	73,039	23,692
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	78,009	22,515	64	92,8	62	96,9	76,882	19,845
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	79,235	24,129	64	92,8	60	93,8	79,074	18,648
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	80,843	22,493	63	91,3	62	98,4	81,720	17,665
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	80,146	21,860	69	100,0	60	87,0	80,370	20,999
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	81,481	26,523	63	91,3	58	92,1	76,724	24,126

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	84,362	21,315	62	89,9	56	90,3	80,754	20,705
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	83,120	22,599	59	85,5	51	86,4	82,353	17,523
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	703	96,6	71,298	23,269	715	100,0	687	96,1	69,675	23,234
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	544	91,9	74,551	22,128	572	80,0	523	91,4	73,072	22,032
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	75,613	22,751	673	94,1	634	94,2	73,379	23,450
WEEK 25	Breast conserving surgery	665	91,3	637	95,8	77,778	22,362	654	91,5	614	93,9	76,620	22,597
END OF TREATMENT	Breast conserving surgery	722	99,2	623	86,3	79,392	21,712	711	99,4	622	87,5	76,063	23,615
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	79,639	21,081	659	92,2	557	84,5	77,309	21,810
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	79,996	21,110	644	90,1	554	86,0	79,041	21,847
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	80,190	22,018	616	86,2	535	86,9	78,484	22,128
BASELINE	Mastectomy	1083	100,0	1057	97,6	74,162	21,641	1107	100,0	1090	98,5	72,997	22,668
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	76,044	21,838	873	78,9	836	95,8	73,558	21,795
WEEK 13	Mastectomy	1011	93,4	968	95,7	76,785	22,261	1051	94,9	1004	95,5	75,105	22,476
WEEK 25	Mastectomy	980	90,5	944	96,3	79,020	20,454	1033	93,3	986	95,5	78,651	20,569
END OF TREATMENT	Mastectomy	1072	99,0	948	88,4	79,946	20,467	1099	99,3	1003	91,3	79,367	21,067
FU MONTH 18	Mastectomy	985	91,0	888	90,2	80,887	20,796	1028	92,9	913	88,8	79,317	21,154
FU MONTH 24	Mastectomy	967	89,3	857	88,6	81,687	20,641	993	89,7	869	87,5	80,060	21,212

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	82,033	21,085	939	84,8	816	86,9	80,018	21,667
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	55,556	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	77,778	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	77,778	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	44,444	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	77,778	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	643	97,4	73,060	22,630	665	100,0	642	96,5	71,002	23,295
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	481	92,7	75,087	21,642	523	78,6	492	94,1	72,640	22,798
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	76,427	22,243	631	94,9	606	96,0	74,312	22,919
WEEK 25	0 - < 2 cm	608	92,1	581	95,6	78,160	21,018	617	92,8	588	95,3	78,553	21,716
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	79,745	20,322	661	99,4	598	90,5	78,948	20,831
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	80,239	19,469	624	93,8	558	89,4	78,435	21,957
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	81,846	19,619	606	91,1	530	87,5	80,304	21,029
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	81,788	20,780	580	87,2	507	87,4	79,531	21,998
BASELINE	>= 2 - < 5 cm	1009	100,0	978	96,9	73,415	21,743	991	100,0	971	98,0	71,742	22,781
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	753	94,5	75,505	21,966	789	79,6	743	94,2	73,306	21,276
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	76,761	21,847	940	94,9	891	94,8	74,118	22,605
WEEK 25	>= 2 - < 5 cm	910	90,2	879	96,6	79,111	21,028	919	92,7	866	94,2	77,643	20,876
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	867	86,9	80,251	20,954	985	99,4	875	88,8	77,524	22,491

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	828	89,7	81,166	21,050	914	92,2	781	85,4	78,333	21,271
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	80,679	21,340	889	89,7	776	87,3	79,095	21,923
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	81,277	21,690	839	84,7	727	86,7	79,008	22,043
BASELINE	>= 5 cm	139	100,0	137	98,6	69,830	25,098	165	100,0	163	98,8	74,165	22,389
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	76,402	23,655	132	80,0	123	93,2	76,468	21,588
WEEK 13	>= 5 cm	130	93,5	124	95,4	72,581	27,269	152	92,1	140	92,1	77,143	24,276
WEEK 25	>= 5 cm	124	89,2	118	95,2	75,800	23,898	150	90,9	145	96,7	76,858	22,434
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	76,044	23,659	163	98,8	151	92,6	78,182	24,428
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	75,389	25,767	148	89,7	130	87,8	80,171	20,191
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	78,979	22,984	141	85,5	116	82,3	80,747	19,841
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	78,218	23,408	135	81,8	115	85,2	81,546	19,848
BASELINE	Missing	3	100,0	2	66,7	83,333	7,857	2	100,0	2	100,0	66,667	47,140
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	81,481	16,973	2	100,0	2	100,0	77,778	31,427
WEEK 13	Missing	3	100,0	3	100,0	77,778	22,222	2	100,0	2	100,0	66,667	15,713
WEEK 25	Missing	3	100,0	3	100,0	81,481	16,973	2	100,0	2	100,0	50,000	54,997
END OF TREATMENT	Missing	3	100,0	3	100,0	77,778	22,222	2	100,0	2	100,0	55,556	62,854
FU MONTH 18	Missing	3	100,0	3	100,0	70,370	27,962	2	100,0	2	100,0	72,222	39,284
FU MONTH 24	Missing	3	100,0	3	100,0	92,593	12,830	2	100,0	2	100,0	66,667	47,140
FU MONTH 36	Missing	3	100,0	3	100,0	100,000	0,000	2	100,0	2	100,0	72,222	39,284
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1318	97,8	72,880	22,716	1350	100,0	1314	97,3	71,178	23,279
END OF ANTHRACYCLINE	Yes	1103	81,9	1045	94,7	75,848	21,942	1104	81,8	1041	94,3	73,754	21,442
WEEK 13	Yes	1308	97,1	1245	95,2	75,984	22,817	1324	98,1	1251	94,5	74,425	22,962
WEEK 25	Yes	1277	94,8	1223	95,8	78,491	21,467	1302	96,4	1229	94,4	77,339	21,958

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1211	89,9	79,305	21,427	1350	100,0	1234	91,4	77,647	22,514
FU MONTH 18	Yes	1291	95,8	1143	88,5	79,975	21,051	1298	96,1	1129	87,0	78,152	21,669
FU MONTH 24	Yes	1266	94,0	1110	87,7	80,190	21,150	1260	93,3	1089	86,4	79,441	21,560
FU MONTH 36	Yes	1219	90,5	1062	87,1	80,780	21,479	1195	88,5	1035	86,6	78,803	22,245
BASELINE	No	464	100,0	442	95,3	73,429	21,212	473	100,0	464	98,1	73,144	21,954
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	73,999	22,002	342	72,3	319	93,3	72,065	23,227
WEEK 13	No	380	81,9	362	95,3	77,471	21,164	401	84,8	388	96,8	74,485	22,556
WEEK 25	No	368	79,3	358	97,3	78,616	20,498	386	81,6	372	96,4	79,630	19,268
END OF TREATMENT	No	447	96,3	360	80,5	81,142	19,290	461	97,5	392	85,0	79,450	20,875
FU MONTH 18	No	372	80,2	339	91,1	81,776	20,407	390	82,5	342	87,7	79,760	20,670
FU MONTH 24	No	367	79,1	323	88,0	83,815	19,511	378	79,9	335	88,6	80,381	21,112
FU MONTH 36	No	352	75,9	329	93,5	82,928	21,425	361	76,3	316	87,5	81,399	20,435
Race													
BASELINE	White	1252	100,0	1205	96,2	70,798	23,010	1255	100,0	1217	97,0	69,670	23,578
END OF ANTHRACYCLINE	White	1010	80,7	930	92,1	74,307	22,362	1018	81,1	939	92,2	71,968	21,968
WEEK 13	White	1158	92,5	1086	93,8	74,770	23,243	1183	94,3	1099	92,9	72,364	24,053
WEEK 25	White	1120	89,5	1061	94,7	76,631	22,246	1150	91,6	1071	93,1	75,921	22,602
END OF TREATMENT	White	1238	98,9	1046	84,5	77,719	22,139	1244	99,1	1087	87,4	75,733	23,531
FU MONTH 18	White	1138	90,9	979	86,0	78,073	22,049	1152	91,8	965	83,8	76,431	22,309
FU MONTH 24	White	1115	89,1	943	84,6	78,644	22,116	1120	89,2	939	83,8	77,748	22,432
FU MONTH 36	White	1071	85,5	923	86,2	79,120	22,932	1064	84,8	898	84,4	77,190	23,102
BASELINE	Black	25	100,0	24	96,0	76,852	24,719	31	100,0	30	96,8	62,222	28,679
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	80,247	14,463	15	48,4	15	100,0	61,481	29,055
WEEK 13	Black	21	84,0	17	81,0	76,471	23,532	29	93,5	28	96,6	64,286	30,892

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	78,947	24,257	29	93,5	28	96,6	68,254	31,239
END OF TREATMENT	Black	24	96,0	22	91,7	82,828	21,062	31	100,0	28	90,3	71,429	30,305
FU MONTH 18	Black	23	92,0	17	73,9	77,124	19,826	29	93,5	24	82,8	69,444	30,074
FU MONTH 24	Black	22	88,0	18	81,8	82,716	23,562	28	90,3	23	82,1	74,396	35,365
FU MONTH 36	Black	22	88,0	18	81,8	82,099	26,166	26	83,9	20	76,9	68,889	36,692
BASELINE	Asian	477	100,0	474	99,4	77,895	19,621	484	100,0	480	99,2	77,338	19,937
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	78,239	20,357	375	77,5	368	98,1	77,355	20,762
WEEK 13	Asian	455	95,4	450	98,9	80,025	19,805	466	96,3	465	99,8	79,904	18,031
WEEK 25	Asian	450	94,3	448	99,6	82,887	17,645	465	96,1	459	98,7	82,898	16,886
END OF TREATMENT	Asian	475	99,6	452	95,2	83,923	17,016	484	100,0	463	95,7	83,765	16,741
FU MONTH 18	Asian	447	93,7	433	96,9	85,271	17,232	461	95,2	441	95,7	83,472	17,996
FU MONTH 24	Asian	442	92,7	423	95,7	85,868	15,896	445	91,9	421	94,6	83,927	17,569
FU MONTH 36	Asian	424	88,9	401	94,6	85,592	16,682	425	87,8	398	93,6	84,562	17,048
BASELINE	Other	52	100,0	52	100,0	78,205	20,041	51	100,0	50	98,0	72,000	21,442
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	77,778	19,772	36	70,6	36	100,0	72,840	22,134
WEEK 13	Other	49	94,2	49	100,0	76,417	23,748	45	88,2	45	100,0	74,321	22,326
WEEK 25	Other	49	94,2	48	98,0	79,167	22,296	42	82,4	41	97,6	78,591	14,988
END OF TREATMENT	Other	52	100,0	47	90,4	82,979	22,083	50	98,0	47	94,0	80,142	19,922
FU MONTH 18	Other	50	96,2	48	96,0	84,491	19,947	44	86,3	39	88,6	79,772	20,051
FU MONTH 24	Other	49	94,2	45	91,8	84,938	23,707	43	84,3	39	90,7	82,621	18,522
FU MONTH 36	Other	49	94,2	44	89,8	86,869	20,372	39	76,5	33	84,6	83,502	14,730
BASELINE	Missing	5	100,0	5	100,0	73,333	35,660	2	100,0	1	50,0	88,889	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	57,778	52,938	2	100,0	2	100,0	88,889	15,713
WEEK 13	Missing	5	100,0	5	100,0	77,778	27,217	2	100,0	2	100,0	88,889	15,713

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	80,000	27,666	2	100,0	2	100,0	88,889	15,713
END OF TREATMENT	Missing	5	100,0	4	80,0	75,000	29,222	2	100,0	1	50,0	88,889	NE
FU MONTH 18	Missing	5	100,0	5	100,0	82,222	24,343	2	100,0	2	100,0	83,333	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	72,222	36,851	2	100,0	2	100,0	83,333	23,570
FU MONTH 36	Missing	5	100,0	5	100,0	84,444	24,343	2	100,0	2	100,0	88,889	15,713

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC03_SG.xls
11AUG2020 15:52

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1761	97,2	88,454	16,793	1823	100,0	1778	97,5	87,936	17,968
END OF ANTHRACYCLINE	n/a	1432	79,1	1343	93,8	82,192	20,324	1446	79,3	1362	94,2	80,751	21,017
WEEK 13	n/a	1688	93,2	1607	95,2	79,558	21,544	1725	94,6	1639	95,0	79,408	21,115
WEEK 25	n/a	1645	90,8	1581	96,1	81,404	20,143	1688	92,6	1601	94,8	81,314	20,045
END OF TREATMENT	n/a	1794	99,1	1571	87,6	81,286	20,792	1811	99,3	1625	89,7	80,913	21,465
FU MONTH 18	n/a	1663	91,8	1482	89,1	82,321	20,130	1688	92,6	1472	87,2	81,703	20,410
FU MONTH 24	n/a	1633	90,2	1433	87,8	82,263	20,555	1638	89,9	1424	86,9	82,151	20,419
FU MONTH 36	n/a	1571	86,7	1391	88,5	83,633	19,672	1556	85,4	1351	86,8	82,976	20,610
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	92,177	17,045	43	100,0	40	93,0	90,000	18,413
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	82,258	21,915	26	60,5	25	96,2	82,667	24,286
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	79,924	19,549	40	93,0	39	97,5	82,051	18,090
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	82,171	24,773	38	88,4	35	92,1	81,905	19,119
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	86,742	18,531	42	97,7	37	88,1	86,036	25,311
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	81,783	22,659	39	90,7	36	92,3	81,944	26,837

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	83,721	22,855	39	90,7	34	87,2	84,804	22,980
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	87,407	17,099	39	90,7	37	94,9	88,739	17,148
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	87,897	19,571	278	100,0	271	97,5	89,545	15,953
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	83,989	17,391	203	73,0	191	94,1	80,192	23,670
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	81,348	21,313	263	94,6	253	96,2	78,920	21,343
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	81,793	20,711	256	92,1	246	96,1	80,962	20,866
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	81,498	21,732	276	99,3	255	92,4	78,758	21,806
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	83,028	19,724	259	93,2	232	89,6	81,250	19,658
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	82,616	22,127	256	92,1	229	89,5	82,460	20,032
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	84,419	20,352	251	90,3	227	90,4	83,480	19,770
BASELINE	1-3 positive nodes	907	100,0	885	97,6	88,475	16,021	900	100,0	878	97,6	87,377	18,592
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	662	92,8	81,923	20,513	707	78,6	667	94,3	81,184	20,350
WEEK 13	1-3 positive nodes	847	93,4	806	95,2	79,363	21,585	854	94,9	806	94,4	79,632	21,513
WEEK 25	1-3 positive nodes	825	91,0	785	95,2	81,401	20,347	836	92,9	790	94,5	81,772	19,346
END OF TREATMENT	1-3 positive nodes	899	99,1	780	86,8	81,047	20,602	897	99,7	810	90,3	81,461	20,790
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	82,111	20,721	852	94,7	742	87,1	81,559	20,071

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	81,593	20,871	830	92,2	726	87,5	82,782	19,664
FU MONTH 36	1-3 positive nodes	804	88,6	704	87,6	83,073	19,787	794	88,2	668	84,1	82,735	20,763
BASELINE	>= 4 positive nodes	596	100,0	575	96,5	88,348	16,622	602	100,0	589	97,8	87,889	17,857
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	81,886	20,995	510	84,7	479	93,9	80,271	20,679
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	79,023	21,760	568	94,4	541	95,2	79,113	20,642
WEEK 25	>= 4 positive nodes	533	89,4	515	96,6	81,165	19,174	558	92,7	530	95,0	80,755	20,767
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	81,090	20,829	596	99,0	523	87,8	80,752	21,987
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	82,371	19,201	538	89,4	462	85,9	82,143	20,809
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	83,039	19,039	513	85,2	435	84,8	80,728	21,606
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	83,763	19,392	472	78,4	419	88,8	82,578	21,071
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1402	97,4	88,600	16,655	1448	100,0	1413	97,6	88,335	17,746
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1341	93,8	82,165	20,328	1444	99,7	1361	94,3	80,762	21,022
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	80,212	21,250	1374	94,9	1304	94,9	80,215	20,907
WEEK 25	Anthracycline containing regimen	1311	91,1	1255	95,7	81,780	20,156	1346	93,0	1276	94,8	81,544	20,240
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	81,263	21,064	1444	99,7	1301	90,1	81,245	21,095

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1183	89,0	82,544	19,795	1340	92,5	1176	87,8	81,959	20,473
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	82,447	20,629	1308	90,3	1135	86,8	82,628	20,201
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1110	88,2	83,904	19,336	1244	85,9	1085	87,2	83,364	20,299
BASELINE	Non-anthracycline containing regimen	372	100,0	359	96,5	87,883	17,334	375	100,0	365	97,3	86,393	18,750
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	100,000	0,000	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	76,878	22,549	351	93,6	335	95,4	76,269	21,654
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	79,959	20,056	342	91,2	325	95,0	80,410	19,267
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	81,376	19,699	367	97,9	324	88,3	79,578	22,877
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	81,438	21,418	348	92,8	296	85,1	80,687	20,158
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	81,527	20,272	330	88,0	289	87,6	80,277	21,184
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	82,562	20,950	312	83,2	266	85,3	81,391	21,800
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	842	97,5	88,717	17,622	858	100,0	840	97,9	88,909	16,844
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	637	94,8	82,575	20,237	661	77,0	621	93,9	80,166	22,276
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	80,069	21,455	804	93,7	773	96,1	79,991	20,394
WEEK 25	Negative (ER and PgR negative)	799	92,5	772	96,6	81,952	19,841	786	91,6	750	95,4	81,444	19,877
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	81,784	20,052	854	99,5	764	89,5	80,432	21,552
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	716	89,4	83,450	19,241	781	91,0	694	88,9	81,916	20,515
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	83,261	19,708	763	88,9	675	88,5	82,543	19,583
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	84,490	18,531	735	85,7	654	89,0	83,869	19,219
BASELINE	Positive (ER and/or PgR positive)	947	100,0	919	97,0	88,212	16,002	965	100,0	938	97,2	87,065	18,885
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	81,846	20,411	785	81,3	741	94,4	81,242	19,903
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	79,081	21,630	921	95,4	866	94,0	78,888	21,737
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	809	95,6	80,882	20,425	902	93,5	851	94,3	81,199	20,204
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	807	86,0	80,814	21,470	957	99,2	861	90,0	81,340	21,391
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	81,266	20,885	907	94,0	778	85,8	81,512	20,327
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	81,326	21,290	875	90,7	749	85,6	81,798	21,151

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	82,820	20,676	821	85,1	697	84,9	82,138	21,815
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	87,339	17,616	260	100,0	255	98,1	84,052	20,929
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	83,007	18,012	111	42,7	105	94,6	76,667	21,006
WEEK 13	USA/Canada	242	91,3	229	94,6	75,546	23,802	236	90,8	224	94,9	74,405	23,615
WEEK 25	USA/Canada	234	88,3	225	96,2	79,778	22,209	230	88,5	219	95,2	79,833	21,068
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	80,787	22,215	255	98,1	229	89,8	80,568	22,880
FU MONTH 18	USA/Canada	238	89,8	194	81,5	80,155	22,824	231	88,8	179	77,5	79,702	23,051
FU MONTH 24	USA/Canada	231	87,2	188	81,4	80,230	24,207	224	86,2	177	79,0	80,508	22,575
FU MONTH 36	USA/Canada	223	84,2	180	80,7	81,759	23,352	205	78,8	156	76,1	82,906	21,582
BASELINE	Western Europe	827	100,0	789	95,4	88,128	17,650	822	100,0	787	95,7	88,585	19,041
END OF ANTHRACYCLINE	Western Europe	732	88,5	665	90,8	80,351	21,816	728	88,6	663	91,1	80,241	22,497
WEEK 13	Western Europe	764	92,4	700	91,6	78,667	22,404	778	94,6	710	91,3	79,272	22,489
WEEK 25	Western Europe	738	89,2	691	93,6	80,101	21,423	750	91,2	680	90,7	81,642	20,765
END OF TREATMENT	Western Europe	821	99,3	691	84,2	78,461	23,217	817	99,4	701	85,8	79,838	23,352
FU MONTH 18	Western Europe	754	91,2	647	85,8	80,319	22,294	764	92,9	630	82,5	81,614	21,578
FU MONTH 24	Western Europe	739	89,4	614	83,1	80,239	22,476	747	90,9	618	82,7	81,850	22,072
FU MONTH 36	Western Europe	713	86,2	613	86,0	82,518	20,967	712	86,6	596	83,7	83,305	21,574
BASELINE	Asia Pacific	490	100,0	487	99,4	88,809	15,667	512	100,0	508	99,2	88,025	15,362
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	83,111	18,608	397	77,5	390	98,2	80,812	18,972
WEEK 13	Asia Pacific	466	95,1	465	99,8	80,609	19,072	493	96,3	492	99,8	80,589	17,570
WEEK 25	Asia Pacific	461	94,1	460	99,8	82,790	17,473	492	96,1	488	99,2	81,079	17,632

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	83,046	16,718	512	100,0	490	95,7	81,599	18,549
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	84,627	15,482	485	94,7	471	97,1	81,847	18,709
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	84,392	15,856	470	91,8	448	95,3	82,812	17,865
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	84,412	16,205	453	88,5	432	95,4	82,523	18,621
BASELINE	Latin America	43	100,0	43	100,0	94,574	10,106	47	100,0	46	97,9	90,580	14,762
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	90,230	19,679	32	68,1	32	100,0	85,938	18,015
WEEK 13	Latin America	40	93,0	40	100,0	86,667	17,378	44	93,6	44	100,0	84,091	18,312
WEEK 25	Latin America	39	90,7	39	100,0	84,188	18,317	44	93,6	44	100,0	83,712	17,046
END OF TREATMENT	Latin America	42	97,7	38	90,5	86,404	20,451	45	95,7	42	93,3	85,317	18,843
FU MONTH 18	Latin America	41	95,3	37	90,2	86,937	19,299	42	89,4	40	95,2	84,167	14,097
FU MONTH 24	Latin America	40	93,0	36	90,0	84,722	21,958	41	87,2	39	95,1	85,043	17,436
FU MONTH 36	Latin America	38	88,4	34	89,5	87,255	16,442	37	78,7	36	97,3	86,574	17,284
BASELINE	Other	186	100,0	184	98,9	89,040	15,750	182	100,0	182	100,0	89,652	15,415
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	85,453	18,556	178	97,8	172	96,6	84,109	19,564
WEEK 13	Other	176	94,6	173	98,3	84,008	20,832	174	95,6	169	97,1	81,953	20,847
WEEK 25	Other	173	93,0	166	96,0	84,538	18,493	172	94,5	170	98,8	81,961	22,893
END OF TREATMENT	Other	185	99,5	162	87,6	87,757	15,957	182	100,0	163	89,6	82,822	19,548
FU MONTH 18	Other	171	91,9	153	89,5	85,621	17,940	166	91,2	152	91,6	83,333	18,498
FU MONTH 24	Other	169	90,9	154	91,1	86,147	18,158	156	85,7	142	91,0	82,629	18,394
FU MONTH 36	Other	160	86,0	147	91,9	87,528	18,283	149	81,9	131	87,9	82,061	22,132
Protocol version													
BASELINE	Protocol A	1240	100,0	1205	97,2	88,575	17,076	1246	100,0	1211	97,2	88,150	17,869

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	915	93,0	82,987	19,370	988	79,3	928	93,9	80,514	21,541
WEEK 13	Protocol A	1155	93,1	1108	95,9	80,144	21,343	1180	94,7	1114	94,4	79,653	21,509
WEEK 25	Protocol A	1125	90,7	1083	96,3	82,179	20,342	1157	92,9	1092	94,4	81,273	20,597
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	82,246	20,598	1236	99,2	1113	90,0	80,698	21,878
FU MONTH 18	Protocol A	1142	92,1	1023	89,6	82,714	20,503	1156	92,8	1003	86,8	81,921	20,714
FU MONTH 24	Protocol A	1124	90,6	995	88,5	82,563	20,879	1127	90,4	979	86,9	82,346	20,534
FU MONTH 36	Protocol A	1087	87,7	980	90,2	84,167	19,590	1069	85,8	934	87,4	83,155	20,991
BASELINE	Protocol Amendment B	571	100,0	556	97,4	88,189	16,176	577	100,0	567	98,3	87,478	18,187
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	80,491	22,155	458	79,4	434	94,8	81,260	19,867
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	78,257	21,949	545	94,5	525	96,3	78,889	20,265
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	79,719	19,618	531	92,0	509	95,9	81,401	18,826
END OF TREATMENT	Protocol Amendment B	565	98,9	498	88,1	79,217	21,074	575	99,7	512	89,0	81,380	20,551
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	81,445	19,268	532	92,2	469	88,2	81,237	19,756
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	81,583	19,807	511	88,6	445	87,1	81,723	20,179
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	82,360	19,833	487	84,4	417	85,6	82,574	19,750
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	88,594	19,221	321	100,0	311	96,9	89,603	16,258
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	83,732	18,084	229	71,3	216	94,3	80,478	23,698
WEEK 13	0 positive nodes	294	95,5	279	94,9	81,123	21,018	303	94,4	292	96,4	79,338	20,937
WEEK 25	0 positive nodes	287	93,2	281	97,9	81,851	21,334	294	91,6	281	95,6	81,079	20,627
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	82,349	21,302	318	99,1	292	91,8	79,680	22,364
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	82,822	20,195	298	92,8	268	89,9	81,343	20,708

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	82,804	22,210	295	91,9	263	89,2	82,763	20,404
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	84,936	19,829	290	90,3	264	91,0	84,217	19,479
BASELINE	>= 1 positive nodes	1503	100,0	1460	97,1	88,425	16,255	1502	100,0	1467	97,7	87,582	18,296
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1134	93,8	81,908	20,706	1217	81,0	1146	94,2	80,803	20,484
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	79,229	21,647	1422	94,7	1347	94,7	79,423	21,161
WEEK 25	>= 1 positive nodes	1358	90,4	1300	95,7	81,308	19,883	1394	92,8	1320	94,7	81,364	19,927
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1300	87,3	81,064	20,685	1493	99,4	1333	89,3	81,183	21,262
FU MONTH 18	>= 1 positive nodes	1371	91,2	1221	89,1	82,214	20,123	1390	92,5	1204	86,6	81,783	20,351
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	82,148	20,192	1343	89,4	1161	86,4	82,013	20,428
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	83,333	19,633	1266	84,3	1087	85,9	82,674	20,873
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	88,453	16,914	885	100,0	868	98,1	88,633	17,503
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	80,769	21,121	726	82,0	693	95,5	80,904	20,843
WEEK 13	Premenopausal	841	96,3	806	95,8	77,750	21,675	852	96,3	809	95,0	79,295	21,161
WEEK 25	Premenopausal	825	94,5	797	96,6	80,155	21,454	838	94,7	800	95,5	81,083	20,077
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	80,363	21,548	881	99,5	809	91,8	80,944	21,281
FU MONTH 18	Premenopausal	819	93,8	724	88,4	81,837	21,194	835	94,4	737	88,3	82,270	19,755
FU MONTH 24	Premenopausal	803	92,0	705	87,8	81,726	21,204	807	91,2	707	87,6	83,498	19,904

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	83,185	20,689	773	87,3	668	86,4	83,383	21,364
BASELINE	Postmenopausal	933	100,0	903	96,8	88,427	16,719	929	100,0	902	97,1	87,324	18,283
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	662	92,1	83,610	19,435	711	76,5	662	93,1	80,564	21,123
WEEK 13	Postmenopausal	842	90,2	797	94,7	81,326	21,303	864	93,0	822	95,1	79,420	21,115
WEEK 25	Postmenopausal	815	87,4	779	95,6	82,649	18,674	841	90,5	794	94,4	81,507	20,083
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	82,152	20,057	921	99,1	808	87,7	80,837	21,723
FU MONTH 18	Postmenopausal	839	89,9	755	90,0	82,737	19,079	844	90,9	727	86,1	81,041	21,106
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	82,758	19,933	823	88,6	712	86,5	80,805	20,896
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	84,009	18,689	776	83,5	677	87,2	82,595	19,827
BASELINE	Unknown/Missing	5	100,0	5	100,0	93,333	9,129	9	100,0	8	88,9	81,250	28,781
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	86,667	13,944	9	100,0	7	77,8	83,333	30,429
WEEK 13	Unknown/Missing	5	100,0	4	80,0	91,667	9,623	9	100,0	8	88,9	89,583	15,269
WEEK 25	Unknown/Missing	5	100,0	5	100,0	86,667	13,944	9	100,0	7	77,8	85,714	11,501
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	83,333	13,608	9	100,0	8	88,9	85,417	13,909
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	94,444	9,623	9	100,0	8	88,9	89,583	12,400
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	87,500	15,957	8	88,9	5	62,5	83,333	11,785
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	91,667	16,667	7	77,8	6	85,7	80,556	24,533
Age II													
BASELINE	< 65	1581	100,0	1542	97,5	88,262	16,968	1604	100,0	1570	97,9	87,941	18,029
END OF ANTHRACYCLINE	< 65	1268	80,2	1198	94,5	82,137	20,460	1287	80,2	1221	94,9	80,399	21,012
WEEK 13	< 65	1497	94,7	1427	95,3	79,841	21,150	1529	95,3	1455	95,2	79,187	21,188

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	81,349	20,296	1501	93,6	1428	95,1	81,373	19,987
END OF TREATMENT	< 65	1569	99,2	1383	88,1	81,007	20,971	1596	99,5	1442	90,4	80,895	21,330
FU MONTH 18	< 65	1474	93,2	1311	88,9	82,482	20,269	1497	93,3	1316	87,9	81,725	20,393
FU MONTH 24	< 65	1446	91,5	1263	87,3	82,423	20,575	1450	90,4	1268	87,4	82,374	20,241
FU MONTH 36	< 65	1390	87,9	1233	88,7	83,698	19,752	1383	86,2	1202	86,9	82,820	20,896
BASELINE	>= 65	230	100,0	219	95,2	89,802	15,478	219	100,0	208	95,0	87,901	17,545
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	82,644	19,233	159	72,6	141	88,7	83,806	20,887
WEEK 13	>= 65	191	83,0	180	94,2	77,315	24,396	196	89,5	184	93,9	81,159	20,500
WEEK 25	>= 65	181	78,7	178	98,3	81,835	18,939	187	85,4	173	92,5	80,829	20,574
END OF TREATMENT	>= 65	225	97,8	188	83,6	83,333	19,348	215	98,2	183	85,1	81,056	22,564
FU MONTH 18	>= 65	189	82,2	171	90,5	81,092	19,042	191	87,2	156	81,7	81,517	20,615
FU MONTH 24	>= 65	187	81,3	170	90,9	81,078	20,428	188	85,8	156	83,0	80,342	21,791
FU MONTH 36	>= 65	181	78,7	158	87,3	83,122	19,090	173	79,0	149	86,1	84,228	18,153
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	87,634	15,497	24	100,0	24	100,0	89,583	16,161
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	76,471	21,294	17	70,8	16	94,1	79,167	16,667
WEEK 13	Grade 1	31	96,9	30	96,8	73,889	25,022	23	95,8	22	95,7	80,303	20,979
WEEK 25	Grade 1	31	96,9	28	90,3	75,595	22,444	23	95,8	22	95,7	78,788	20,041
END OF TREATMENT	Grade 1	31	96,9	27	87,1	79,630	25,036	24	100,0	21	87,5	74,603	26,151
FU MONTH 18	Grade 1	30	93,8	27	90,0	80,247	23,587	23	95,8	22	95,7	79,545	24,087
FU MONTH 24	Grade 1	28	87,5	27	96,4	77,778	23,113	23	95,8	21	91,3	77,778	24,343
FU MONTH 36	Grade 1	27	84,4	26	96,3	81,410	26,385	22	91,7	20	90,9	81,667	24,721
BASELINE	Grade 2	552	100,0	536	97,1	89,179	14,943	557	100,0	543	97,5	87,354	18,102
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	83,176	19,972	446	80,1	424	95,1	81,289	20,495

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	80,658	20,243	524	94,1	504	96,2	79,894	21,261
WEEK 25	Grade 2	494	89,5	479	97,0	82,707	19,002	515	92,5	492	95,5	81,877	19,918
END OF TREATMENT	Grade 2	548	99,3	485	88,5	81,100	20,473	553	99,3	495	89,5	81,785	21,073
FU MONTH 18	Grade 2	507	91,8	456	89,9	82,602	19,442	517	92,8	447	86,5	81,320	20,872
FU MONTH 24	Grade 2	501	90,8	449	89,6	82,368	20,329	500	89,8	431	86,2	83,179	19,948
FU MONTH 36	Grade 2	487	88,2	437	89,7	84,630	18,708	476	85,5	414	87,0	82,890	20,267
BASELINE	Grade 3	1161	100,0	1131	97,4	88,167	17,591	1173	100,0	1143	97,4	88,189	17,959
END OF ANTHRACYCLINE	Grade 3	918	79,1	855	93,1	81,696	20,450	919	78,3	860	93,6	80,388	21,467
WEEK 13	Grade 3	1088	93,7	1030	94,7	79,207	21,747	1114	95,0	1053	94,5	79,202	20,988
WEEK 25	Grade 3	1059	91,2	1016	95,9	80,938	20,268	1087	92,7	1025	94,3	80,959	20,287
END OF TREATMENT	Grade 3	1150	99,1	998	86,8	81,480	20,488	1165	99,3	1049	90,0	80,759	21,641
FU MONTH 18	Grade 3	1067	91,9	945	88,6	82,310	20,140	1085	92,5	945	87,1	82,116	20,092
FU MONTH 24	Grade 3	1046	90,1	903	86,3	82,263	20,512	1053	89,8	916	87,0	81,932	20,546
FU MONTH 36	Grade 3	1002	86,3	876	87,4	83,086	19,847	999	85,2	866	86,7	83,141	20,759
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	87,831	17,761	69	100,0	68	98,6	87,745	17,894
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	84,375	20,744	64	92,8	62	96,9	82,527	19,424
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	79,508	25,890	64	92,8	60	93,8	78,611	22,569
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	81,609	25,110	63	91,3	62	98,4	83,602	16,936
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	80,328	26,089	69	100,0	60	87,0	78,611	19,670
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	81,173	24,021	63	91,3	58	92,1	78,736	20,660

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	83,642	22,075	62	89,9	56	90,3	79,464	20,348
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	85,577	20,882	59	85,5	51	86,4	81,373	19,621
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	704	96,7	88,258	17,013	715	100,0	687	96,1	88,258	18,454
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	545	92,1	82,080	19,776	572	80,0	523	91,4	81,294	20,686
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	78,925	22,457	673	94,1	634	94,2	79,784	21,386
WEEK 25	Breast conserving surgery	665	91,3	637	95,8	81,345	21,546	654	91,5	614	93,9	80,646	21,277
END OF TREATMENT	Breast conserving surgery	722	99,2	623	86,3	81,300	21,455	711	99,4	621	87,3	79,898	22,813
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	82,295	20,947	659	92,2	558	84,7	80,914	21,082
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	81,510	21,915	644	90,1	554	86,0	83,363	19,983
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	83,541	20,647	616	86,2	535	86,9	83,925	20,302
BASELINE	Mastectomy	1083	100,0	1057	97,6	88,584	16,652	1107	100,0	1090	98,5	87,737	17,669
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	82,268	20,703	873	78,9	838	96,0	80,390	21,228
WEEK 13	Mastectomy	1011	93,4	968	95,7	79,976	20,921	1051	94,9	1004	95,5	79,150	20,950
WEEK 25	Mastectomy	980	90,5	944	96,3	81,444	19,149	1033	93,3	986	95,5	81,711	19,240
END OF TREATMENT	Mastectomy	1072	99,0	948	88,4	81,276	20,355	1099	99,3	1003	91,3	81,555	20,579
FU MONTH 18	Mastectomy	985	91,0	888	90,2	82,339	19,577	1028	92,9	913	88,8	82,183	19,995
FU MONTH 24	Mastectomy	967	89,3	857	88,6	82,769	19,585	993	89,7	869	87,5	81,358	20,668

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	83,695	18,996	939	84,8	816	86,9	82,353	20,798
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	644	97,6	88,354	17,285	665	100,0	642	96,5	88,655	17,286
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	482	92,9	82,331	19,718	523	78,6	493	94,3	80,122	22,374
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	80,080	21,205	631	94,9	606	96,0	80,006	21,178
WEEK 25	0 - < 2 cm	608	92,1	581	95,6	81,297	20,299	617	92,8	588	95,3	81,321	19,824
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	81,192	20,671	661	99,4	597	90,3	82,217	19,966
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	83,180	19,469	624	93,8	558	89,4	81,930	19,887
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	82,990	20,403	606	91,1	530	87,5	82,862	19,479
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	84,444	19,975	580	87,2	507	87,4	83,366	20,169
BASELINE	>= 2 - < 5 cm	1009	100,0	978	96,9	88,667	16,338	991	100,0	971	98,0	87,624	17,922
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	753	94,5	82,382	20,417	789	79,6	743	94,2	80,933	20,271
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	79,799	21,035	940	94,9	891	94,8	78,601	21,486
WEEK 25	>= 2 - < 5 cm	910	90,2	879	96,6	81,570	20,054	919	92,7	866	94,2	81,197	20,312
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	867	86,9	81,507	20,581	985	99,4	875	88,8	80,057	22,339

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	828	89,7	82,206	20,311	914	92,2	782	85,6	81,138	20,757
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	81,592	20,956	889	89,7	776	87,3	81,723	20,960
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	83,202	19,427	839	84,7	727	86,7	82,760	20,684
BASELINE	>= 5 cm	139	100,0	137	98,6	87,226	17,766	165	100,0	163	98,8	87,014	20,706
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	80,476	22,103	132	80,0	124	93,9	82,258	19,794
WEEK 13	>= 5 cm	130	93,5	124	95,4	75,403	26,069	152	92,1	140	92,1	82,143	18,064
WEEK 25	>= 5 cm	124	89,2	118	95,2	80,650	20,322	150	90,9	145	96,7	82,414	19,122
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	80,133	22,963	163	98,8	151	92,6	81,015	21,691
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	78,816	21,907	148	89,7	130	87,8	84,359	20,413
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	83,033	18,393	141	85,5	116	82,3	82,040	20,984
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	82,508	20,052	135	81,8	115	85,2	83,043	21,852
BASELINE	Missing	3	100,0	2	66,7	100,000	0,000	2	100,0	2	100,0	83,333	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	72,222	34,694	2	100,0	2	100,0	75,000	35,355
WEEK 13	Missing	3	100,0	3	100,0	77,778	25,459	2	100,0	2	100,0	66,667	23,570
WEEK 25	Missing	3	100,0	3	100,0	83,333	16,667	2	100,0	2	100,0	50,000	23,570
END OF TREATMENT	Missing	3	100,0	3	100,0	83,333	16,667	2	100,0	2	100,0	58,333	35,355
FU MONTH 18	Missing	3	100,0	3	100,0	83,333	16,667	2	100,0	2	100,0	66,667	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	100,000	0,000	2	100,0	2	100,0	66,667	23,570
FU MONTH 36	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	58,333	35,355
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1319	97,9	88,527	16,571	1350	100,0	1314	97,3	88,064	18,138
END OF ANTHRACYCLINE	Yes	1103	81,9	1046	94,8	82,234	19,824	1104	81,8	1043	94,5	80,968	20,864
WEEK 13	Yes	1308	97,1	1245	95,2	79,076	21,617	1324	98,1	1251	94,5	79,536	21,040
WEEK 25	Yes	1277	94,8	1223	95,8	81,262	20,167	1302	96,4	1229	94,4	81,231	20,553

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1211	89,9	81,007	21,002	1350	100,0	1233	91,3	80,752	22,014
FU MONTH 18	Yes	1291	95,8	1143	88,5	82,196	19,952	1298	96,1	1130	87,1	82,050	20,835
FU MONTH 24	Yes	1266	94,0	1110	87,7	82,057	20,516	1260	93,3	1089	86,4	82,492	20,439
FU MONTH 36	Yes	1219	90,5	1062	87,1	83,427	19,948	1195	88,5	1035	86,6	83,317	20,570
BASELINE	No	464	100,0	442	95,3	88,235	17,456	473	100,0	464	98,1	87,572	17,492
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	82,043	22,031	342	72,3	319	93,3	80,042	21,528
WEEK 13	No	380	81,9	362	95,3	81,215	21,237	401	84,8	388	96,8	78,995	21,378
WEEK 25	No	368	79,3	358	97,3	81,890	20,082	386	81,6	372	96,4	81,586	18,292
END OF TREATMENT	No	447	96,3	360	80,5	82,222	20,066	461	97,5	392	85,0	81,420	19,656
FU MONTH 18	No	372	80,2	339	91,1	82,743	20,743	390	82,5	342	87,7	80,556	18,921
FU MONTH 24	No	367	79,1	323	88,0	82,972	20,703	378	79,9	335	88,6	81,045	20,345
FU MONTH 36	No	352	75,9	329	93,5	84,296	18,768	361	76,3	316	87,5	81,857	20,734
Race													
BASELINE	White	1252	100,0	1206	96,3	88,032	17,616	1255	100,0	1217	97,0	87,990	18,823
END OF ANTHRACYCLINE	White	1010	80,7	931	92,2	81,651	20,915	1018	81,1	941	92,4	80,517	21,988
WEEK 13	White	1158	92,5	1086	93,8	78,975	22,456	1183	94,3	1099	92,9	78,784	22,438
WEEK 25	White	1120	89,5	1061	94,7	80,851	21,060	1150	91,6	1071	93,1	81,466	20,900
END OF TREATMENT	White	1238	98,9	1046	84,5	80,465	22,432	1244	99,1	1086	87,3	80,325	22,890
FU MONTH 18	White	1138	90,9	979	86,0	81,597	21,696	1152	91,8	965	83,8	81,572	21,386
FU MONTH 24	White	1115	89,1	943	84,6	81,495	22,354	1120	89,2	939	83,8	81,665	21,359
FU MONTH 36	White	1071	85,5	923	86,2	83,297	21,130	1064	84,8	898	84,4	82,944	21,756
BASELINE	Black	25	100,0	24	96,0	89,583	16,161	31	100,0	30	96,8	80,556	23,604
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	81,481	21,155	15	48,4	15	100,0	74,444	23,458
WEEK 13	Black	21	84,0	17	81,0	79,412	22,461	29	93,5	28	96,6	64,881	29,516

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	84,211	21,136	29	93,5	28	96,6	77,381	22,777
END OF TREATMENT	Black	24	96,0	22	91,7	84,091	18,168	31	100,0	28	90,3	73,810	27,378
FU MONTH 18	Black	23	92,0	17	73,9	77,451	22,777	29	93,5	24	82,8	73,611	25,020
FU MONTH 24	Black	22	88,0	18	81,8	79,630	18,573	28	90,3	23	82,1	78,986	25,235
FU MONTH 36	Black	22	88,0	18	81,8	81,481	22,058	26	83,9	20	76,9	75,833	28,855
BASELINE	Asian	477	100,0	474	99,4	88,889	15,160	484	100,0	480	99,2	87,951	15,535
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	83,102	18,900	375	77,5	368	98,1	81,250	18,419
WEEK 13	Asian	455	95,4	450	98,9	80,185	19,600	466	96,3	465	99,8	81,111	16,947
WEEK 25	Asian	450	94,3	448	99,6	82,106	18,055	465	96,1	459	98,7	80,937	17,971
END OF TREATMENT	Asian	475	99,6	452	95,2	82,633	16,836	484	100,0	463	95,7	82,361	17,398
FU MONTH 18	Asian	447	93,7	433	96,9	83,834	16,169	461	95,2	442	95,9	82,089	18,315
FU MONTH 24	Asian	442	92,7	423	95,7	83,806	16,056	445	91,9	421	94,6	83,056	18,201
FU MONTH 36	Asian	424	88,9	401	94,6	84,248	16,133	425	87,8	398	93,6	82,956	17,522
BASELINE	Other	52	100,0	52	100,0	93,590	9,986	51	100,0	50	98,0	91,333	13,145
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	88,288	16,133	36	70,6	36	100,0	84,259	19,084
WEEK 13	Other	49	94,2	49	100,0	86,054	17,128	45	88,2	45	100,0	85,185	15,579
WEEK 25	Other	49	94,2	48	98,0	85,069	17,944	42	82,4	41	97,6	83,740	17,673
END OF TREATMENT	Other	52	100,0	47	90,4	84,752	18,001	50	98,0	47	94,0	84,397	18,845
FU MONTH 18	Other	50	96,2	48	96,0	84,028	18,179	44	86,3	39	88,6	85,470	13,344
FU MONTH 24	Other	49	94,2	45	91,8	84,444	19,592	43	84,3	39	90,7	85,470	16,745
FU MONTH 36	Other	49	94,2	44	89,8	85,227	16,942	39	76,5	33	84,6	87,374	16,682
BASELINE	Missing	5	100,0	5	100,0	90,000	14,907	2	100,0	1	50,0	66,667	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	73,333	30,277	2	100,0	2	100,0	83,333	23,570
WEEK 13	Missing	5	100,0	5	100,0	86,667	13,944	2	100,0	2	100,0	100,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	90,000	9,129	2	100,0	2	100,0	91,667	11,785
END OF TREATMENT	Missing	5	100,0	4	80,0	87,500	15,957	2	100,0	1	50,0	83,333	NE
FU MONTH 18	Missing	5	100,0	5	100,0	93,333	9,129	2	100,0	2	100,0	83,333	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	87,500	15,957	2	100,0	2	100,0	91,667	11,785
FU MONTH 36	Missing	5	100,0	5	100,0	90,000	14,907	2	100,0	2	100,0	100,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC04_SG.xls
11AUG2020 15:54

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Social Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1760	97,2	81,146	23,269	1823	100,0	1775	97,4	80,451	24,050
END OF ANTHRACYCLINE	n/a	1432	79,1	1342	93,7	75,832	24,118	1446	79,3	1362	94,2	74,156	25,117
WEEK 13	n/a	1688	93,2	1606	95,1	73,059	25,866	1725	94,6	1639	95,0	73,154	25,690
WEEK 25	n/a	1645	90,8	1580	96,0	79,589	23,634	1688	92,6	1601	94,8	80,283	23,294
END OF TREATMENT	n/a	1794	99,1	1571	87,6	83,864	21,963	1811	99,3	1625	89,7	83,056	22,999
FU MONTH 18	n/a	1663	91,8	1482	89,1	86,347	21,285	1688	92,6	1471	87,1	84,829	22,055
FU MONTH 24	n/a	1633	90,2	1433	87,8	87,323	20,625	1638	89,9	1424	86,9	87,008	20,914
FU MONTH 36	n/a	1571	86,7	1391	88,5	88,581	19,660	1556	85,4	1351	86,8	87,577	21,133
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	86,395	22,483	43	100,0	40	93,0	81,667	27,940
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	74,731	25,045	26	60,5	25	96,2	66,667	31,549
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	76,894	24,699	40	93,0	39	97,5	67,521	29,107
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	80,233	26,038	38	88,4	35	92,1	81,905	23,699
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	88,636	15,983	42	97,7	37	88,1	86,937	26,683
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	91,473	16,814	39	90,7	36	92,3	86,111	25,355

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	89,535	18,193	39	90,7	34	87,2	90,686	18,437
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	92,593	17,246	39	90,7	37	94,9	93,694	12,639
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	84,458	22,754	278	100,0	271	97,5	83,087	22,905
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	78,371	21,452	203	73,0	191	94,1	75,131	25,240
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	74,681	24,765	263	94,6	253	96,2	74,638	25,997
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	82,138	22,803	256	92,1	246	96,1	81,572	23,696
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	85,977	21,218	276	99,3	255	92,4	82,876	23,309
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	87,462	21,486	259	93,2	232	89,6	85,201	22,395
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	90,271	18,875	256	92,1	229	89,5	89,374	19,588
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	215	90,7	91,008	17,775	251	90,3	227	90,4	88,546	21,634
BASELINE	1-3 positive nodes	907	100,0	885	97,6	81,695	22,979	900	100,0	876	97,3	80,365	24,157
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	661	92,7	76,046	24,053	707	78,6	667	94,3	74,513	24,269
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	72,899	26,105	854	94,9	806	94,4	72,953	25,842
WEEK 25	1-3 positive nodes	825	91,0	785	95,2	80,531	22,789	836	92,9	790	94,5	80,232	23,252
END OF TREATMENT	1-3 positive nodes	899	99,1	780	86,8	84,338	21,315	897	99,7	810	90,3	83,868	21,934
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	87,002	20,188	852	94,7	742	87,1	85,624	21,245

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	728	88,0	87,363	20,682	830	92,2	726	87,5	87,534	20,027
FU MONTH 36	1-3 positive nodes	804	88,6	704	87,6	88,305	20,010	794	88,2	668	84,1	87,849	20,448
BASELINE	>= 4 positive nodes	596	100,0	574	96,3	78,397	23,731	602	100,0	588	97,7	79,280	24,089
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	74,647	25,071	510	84,7	479	93,9	73,660	25,859
WEEK 13	>= 4 positive nodes	547	91,8	522	95,4	72,254	26,086	568	94,4	541	95,2	73,167	25,059
WEEK 25	>= 4 positive nodes	533	89,4	515	96,6	76,926	24,863	558	92,7	530	95,0	79,654	23,179
END OF TREATMENT	>= 4 positive nodes	590	99,0	520	88,1	81,827	23,488	596	99,0	523	87,8	81,612	24,133
FU MONTH 18	>= 4 positive nodes	533	89,4	485	91,0	84,399	22,991	538	89,4	461	85,7	83,261	22,868
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	85,688	21,397	513	85,2	435	84,8	84,598	22,944
FU MONTH 36	>= 4 positive nodes	484	81,2	427	88,2	87,393	20,118	472	78,4	419	88,8	86,078	22,409
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1402	97,4	81,515	23,147	1448	100,0	1410	97,4	81,028	23,795
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1340	93,8	75,821	24,126	1444	99,7	1361	94,3	74,161	25,126
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	74,020	25,561	1374	94,9	1304	94,9	74,450	25,435
WEEK 25	Anthracycline containing regimen	1311	91,1	1255	95,7	80,359	23,277	1346	93,0	1276	94,8	81,897	22,300
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	84,275	21,626	1444	99,7	1300	90,0	83,423	22,875

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1183	89,0	86,700	20,945	1340	92,5	1175	87,7	85,404	21,687
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1147	87,8	87,257	20,669	1308	90,3	1135	86,8	87,210	20,743
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1110	88,2	88,303	19,756	1244	85,9	1085	87,2	87,865	21,205
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	79,702	23,718	375	100,0	365	97,3	78,219	24,918
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	83,333	23,570	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	69,108	26,766	351	93,6	335	95,4	68,109	26,090
WEEK 25	Non-anthracycline containing regimen	334	89,8	325	97,3	76,615	24,779	342	91,2	325	95,0	73,949	25,925
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	82,222	23,222	367	97,9	325	88,6	81,590	23,469
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	84,950	22,564	348	92,8	296	85,1	82,545	23,356
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	87,587	20,481	330	88,0	289	87,6	86,217	21,592
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	89,680	19,269	312	83,2	266	85,3	86,404	20,831
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	841	97,3	81,807	23,598	858	100,0	839	97,8	80,910	24,155
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	637	94,8	75,824	24,619	661	77,0	621	93,9	72,732	26,955
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	73,454	25,787	804	93,7	773	96,1	73,502	25,527
WEEK 25	Negative (ER and PgR negative)	799	92,5	771	96,5	80,480	22,819	786	91,6	750	95,4	80,756	22,754
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	84,533	21,579	854	99,5	764	89,5	83,617	22,388
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	716	89,4	86,965	21,119	781	91,0	693	88,7	85,017	22,229
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	88,232	19,411	763	88,9	675	88,5	87,926	20,631
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	677	89,9	89,636	18,099	735	85,7	654	89,0	88,481	20,847
BASELINE	Positive (ER and/or PgR positive)	947	100,0	919	97,0	80,540	22,960	965	100,0	936	97,0	80,039	23,960
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	705	92,8	75,839	23,674	785	81,3	741	94,4	75,349	23,418
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	830	95,1	72,691	25,949	921	95,4	866	94,0	72,844	25,845
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	809	95,6	78,739	24,370	902	93,5	851	94,3	79,867	23,765
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	807	86,0	83,230	22,316	957	99,2	861	90,0	82,559	23,530
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	85,770	21,437	907	94,0	778	85,8	84,662	21,912
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	739	87,4	86,468	21,681	875	90,7	749	85,6	86,182	21,146

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	87,582	20,997	821	85,1	697	84,9	86,729	21,378
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	81,266	24,778	260	100,0	254	97,7	76,444	28,535
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	72,386	25,096	111	42,7	105	94,6	69,206	27,129
WEEK 13	USA/Canada	242	91,3	228	94,2	68,056	27,442	236	90,8	224	94,9	68,676	28,229
WEEK 25	USA/Canada	234	88,3	224	95,7	77,679	24,711	230	88,5	219	95,2	77,093	26,068
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	84,568	23,647	255	98,1	229	89,8	82,606	26,063
FU MONTH 18	USA/Canada	238	89,8	194	81,5	86,168	22,166	231	88,8	179	77,5	85,102	23,931
FU MONTH 24	USA/Canada	231	87,2	188	81,4	86,968	23,127	224	86,2	177	79,0	87,382	22,139
FU MONTH 36	USA/Canada	223	84,2	180	80,7	89,352	19,520	205	78,8	156	76,1	88,355	21,371
BASELINE	Western Europe	827	100,0	788	95,3	81,176	24,036	822	100,0	785	95,5	83,015	23,740
END OF ANTHRACYCLINE	Western Europe	732	88,5	664	90,7	74,121	25,860	728	88,6	663	91,1	73,605	26,097
WEEK 13	Western Europe	764	92,4	700	91,6	71,905	27,470	778	94,6	710	91,3	72,582	27,100
WEEK 25	Western Europe	738	89,2	691	93,6	79,016	25,241	750	91,2	680	90,7	81,544	23,018
END OF TREATMENT	Western Europe	821	99,3	691	84,2	82,200	23,790	817	99,4	701	85,8	82,929	23,976
FU MONTH 18	Western Europe	754	91,2	647	85,8	85,033	23,600	764	92,9	630	82,5	84,974	22,865
FU MONTH 24	Western Europe	739	89,4	614	83,1	86,455	22,763	747	90,9	618	82,7	87,540	21,225
FU MONTH 36	Western Europe	713	86,2	613	86,0	86,569	22,404	712	86,6	596	83,7	87,472	21,685
BASELINE	Asia Pacific	490	100,0	487	99,4	80,219	21,754	512	100,0	508	99,2	77,854	22,550
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	77,496	20,981	397	77,5	390	98,2	73,889	23,627
WEEK 13	Asia Pacific	466	95,1	465	99,8	74,659	22,927	493	96,3	492	99,8	74,492	22,546
WEEK 25	Asia Pacific	461	94,1	460	99,8	80,145	21,093	492	96,1	488	99,2	79,577	21,616

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	83,980	19,276	512	100,0	490	95,7	83,401	20,280
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	86,290	18,787	485	94,7	470	96,9	84,468	20,007
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	87,113	17,755	470	91,8	448	95,3	85,826	20,267
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	89,369	16,390	453	88,5	432	95,4	87,461	20,695
BASELINE	Latin America	43	100,0	43	100,0	87,209	19,866	47	100,0	46	97,9	78,623	20,081
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	87,356	15,207	32	68,1	32	100,0	85,417	22,300
WEEK 13	Latin America	40	93,0	40	100,0	82,500	18,471	44	93,6	44	100,0	70,455	27,105
WEEK 25	Latin America	39	90,7	39	100,0	88,034	16,644	44	93,6	44	100,0	78,409	25,563
END OF TREATMENT	Latin America	42	97,7	38	90,5	92,982	12,026	45	95,7	42	93,3	84,921	17,580
FU MONTH 18	Latin America	41	95,3	37	90,2	95,495	12,819	42	89,4	40	95,2	82,083	23,986
FU MONTH 24	Latin America	40	93,0	36	90,0	96,759	8,746	41	87,2	39	95,1	88,889	19,245
FU MONTH 36	Latin America	38	88,4	34	89,5	96,569	9,864	37	78,7	36	97,3	90,741	14,055
BASELINE	Other	186	100,0	184	98,9	81,884	22,334	182	100,0	182	100,0	82,692	22,117
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	78,902	23,217	178	97,8	172	96,6	77,810	22,875
WEEK 13	Other	176	94,6	173	98,3	77,842	24,452	174	95,6	169	97,1	78,304	23,274
WEEK 25	Other	173	93,0	166	96,0	81,024	22,985	172	94,5	170	98,8	81,863	24,382
END OF TREATMENT	Other	185	99,5	162	87,6	87,551	19,598	182	100,0	163	89,6	82,720	23,269
FU MONTH 18	Other	171	91,9	153	89,5	90,087	17,253	166	91,2	152	91,6	85,746	22,072
FU MONTH 24	Other	169	90,9	154	91,1	89,610	17,264	156	85,7	142	91,0	87,441	20,551
FU MONTH 36	Other	160	86,0	147	91,9	91,950	16,593	149	81,9	131	87,9	86,641	21,525
Protocol version													
BASELINE	Protocol A	1240	100,0	1205	97,2	81,646	23,647	1246	100,0	1209	97,0	81,348	23,740

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	914	92,9	76,495	24,489	988	79,3	928	93,9	74,407	25,563
WEEK 13	Protocol A	1155	93,1	1108	95,9	74,097	25,620	1180	94,7	1114	94,4	73,459	26,647
WEEK 25	Protocol A	1125	90,7	1082	96,2	80,591	23,541	1157	92,9	1092	94,4	80,998	23,209
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	85,151	21,861	1236	99,2	1113	90,0	83,498	22,766
FU MONTH 18	Protocol A	1142	92,1	1023	89,6	87,064	21,783	1156	92,8	1002	86,7	85,729	21,932
FU MONTH 24	Protocol A	1124	90,6	995	88,5	87,906	20,692	1127	90,4	979	86,9	87,794	20,474
FU MONTH 36	Protocol A	1087	87,7	980	90,2	89,490	19,501	1069	85,8	934	87,4	88,597	20,473
BASELINE	Protocol Amendment B	571	100,0	555	97,2	80,060	22,410	577	100,0	566	98,1	78,534	24,612
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	74,416	23,271	458	79,4	434	94,8	73,618	24,155
WEEK 13	Protocol Amendment B	533	93,3	498	93,4	70,750	26,284	545	94,5	525	96,3	72,508	23,542
WEEK 25	Protocol Amendment B	520	91,1	498	95,8	77,410	23,713	531	92,0	509	95,9	78,749	23,425
END OF TREATMENT	Protocol Amendment B	565	98,9	498	88,1	81,091	21,949	575	99,7	512	89,0	82,096	23,491
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	84,749	20,063	532	92,2	469	88,2	82,907	22,218
FU MONTH 24	Protocol Amendment B	509	89,1	438	86,1	85,997	20,433	511	88,6	445	87,1	85,281	21,776
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	86,415	19,890	487	84,4	417	85,6	85,292	22,397
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	84,773	22,685	321	100,0	311	96,9	82,905	23,566
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	77,831	21,994	229	71,3	216	94,3	74,151	26,105
WEEK 13	0 positive nodes	294	95,5	279	94,9	75,030	24,724	303	94,4	292	96,4	73,687	26,491
WEEK 25	0 positive nodes	287	93,2	280	97,6	81,845	23,289	294	91,6	281	95,6	81,613	23,654
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	86,408	20,457	318	99,1	292	91,8	83,390	23,752
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	88,123	20,813	298	92,8	268	89,9	85,323	22,766

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	90,146	18,727	295	91,9	263	89,2	89,544	19,414
FU MONTH 36	0 positive nodes	283	91,9	260	91,9	91,282	17,662	290	90,3	264	91,0	89,268	20,670
BASELINE	>= 1 positive nodes	1503	100,0	1459	97,1	80,398	23,325	1502	100,0	1464	97,5	79,929	24,127
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1133	93,7	75,463	24,481	1217	81,0	1146	94,2	74,156	24,938
WEEK 13	>= 1 positive nodes	1394	92,7	1327	95,2	72,645	26,090	1422	94,7	1347	94,7	73,039	25,521
WEEK 25	>= 1 positive nodes	1358	90,4	1300	95,7	79,103	23,689	1394	92,8	1320	94,7	80,000	23,216
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1300	87,3	83,333	22,235	1493	99,4	1333	89,3	82,983	22,840
FU MONTH 18	>= 1 positive nodes	1371	91,2	1221	89,1	85,968	21,374	1390	92,5	1203	86,5	84,719	21,902
FU MONTH 24	>= 1 positive nodes	1343	89,4	1181	87,9	86,720	20,966	1343	89,4	1161	86,4	86,434	21,205
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	87,961	20,047	1266	84,3	1087	85,9	87,167	21,232
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	79,308	24,213	885	100,0	866	97,9	78,695	24,241
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	74,679	24,129	726	82,0	693	95,5	74,122	24,647
WEEK 13	Premenopausal	841	96,3	805	95,7	71,967	25,746	852	96,3	809	95,0	73,012	25,170
WEEK 25	Premenopausal	825	94,5	797	96,6	78,043	24,261	838	94,7	800	95,5	79,750	23,356
END OF TREATMENT	Premenopausal	866	99,2	763	88,1	83,355	21,778	881	99,5	810	91,9	82,819	22,967
FU MONTH 18	Premenopausal	819	93,8	724	88,4	85,290	22,133	835	94,4	736	88,1	84,579	21,586
FU MONTH 24	Premenopausal	803	92,0	705	87,8	86,643	21,229	807	91,2	707	87,6	87,364	20,167

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	88,194	19,588	773	87,3	668	86,4	87,849	20,407
BASELINE	Postmenopausal	933	100,0	902	96,7	82,853	22,246	929	100,0	901	97,0	82,168	23,822
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	661	91,9	76,979	24,117	711	76,5	662	93,1	74,068	25,681
WEEK 13	Postmenopausal	842	90,2	797	94,7	74,153	26,014	864	93,0	822	95,1	73,277	26,264
WEEK 25	Postmenopausal	815	87,4	778	95,5	81,148	22,898	841	90,5	794	94,4	80,814	23,300
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	84,432	22,050	921	99,1	807	87,6	83,333	23,083
FU MONTH 18	Postmenopausal	839	89,9	755	90,0	87,351	20,423	844	90,9	727	86,1	85,076	22,593
FU MONTH 24	Postmenopausal	825	88,4	724	87,8	87,960	20,039	823	88,6	712	86,5	86,681	21,601
FU MONTH 36	Postmenopausal	801	85,9	715	89,3	88,904	19,775	776	83,5	677	87,2	87,272	21,891
BASELINE	Unknown/Missing	5	100,0	5	100,0	86,667	18,257	9	100,0	8	88,9	77,083	15,269
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	80,000	18,257	9	100,0	7	77,8	85,714	14,996
WEEK 13	Unknown/Missing	5	100,0	4	80,0	75,000	9,623	9	100,0	8	88,9	75,000	19,920
WEEK 25	Unknown/Missing	5	100,0	5	100,0	83,333	23,570	9	100,0	7	77,8	80,952	14,996
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	66,667	36,004	9	100,0	8	88,9	79,167	19,416
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	88,889	19,245	9	100,0	8	88,9	85,417	16,517
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	91,667	16,667	8	88,9	5	62,5	83,333	28,868
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	95,833	8,333	7	77,8	6	85,7	91,667	13,944
Age II													
BASELINE	< 65	1581	100,0	1542	97,5	80,534	23,446	1604	100,0	1567	97,7	79,909	24,164
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	75,634	24,094	1287	80,2	1221	94,9	73,792	25,081
WEEK 13	< 65	1497	94,7	1426	95,3	73,481	25,427	1529	95,3	1455	95,2	72,990	25,712

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	79,318	23,682	1501	93,6	1428	95,1	80,252	23,326
END OF TREATMENT	< 65	1569	99,2	1383	88,1	84,141	21,575	1596	99,5	1443	90,4	82,814	23,031
FU MONTH 18	< 65	1474	93,2	1311	88,9	86,156	21,374	1497	93,3	1315	87,8	84,626	22,213
FU MONTH 24	< 65	1446	91,5	1263	87,3	87,213	20,544	1450	90,4	1268	87,4	86,961	20,782
FU MONTH 36	< 65	1390	87,9	1233	88,7	88,727	19,404	1383	86,2	1202	86,9	87,354	21,357
BASELINE	>= 65	230	100,0	218	94,8	85,474	21,538	219	100,0	208	95,0	84,535	22,816
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	77,471	24,338	159	72,6	141	88,7	77,305	25,298
WEEK 13	>= 65	191	83,0	180	94,2	69,722	28,973	196	89,5	184	93,9	74,457	25,542
WEEK 25	>= 65	181	78,7	177	97,8	81,733	23,212	187	85,4	173	92,5	80,539	23,090
END OF TREATMENT	>= 65	225	97,8	188	83,6	81,826	24,602	215	98,2	182	84,7	84,982	22,715
FU MONTH 18	>= 65	189	82,2	171	90,5	87,817	20,597	191	87,2	156	81,7	86,538	20,662
FU MONTH 24	>= 65	187	81,3	170	90,9	88,137	21,256	188	85,8	156	83,0	87,393	22,027
FU MONTH 36	>= 65	181	78,7	158	87,3	87,447	21,587	173	79,0	149	86,1	89,374	19,201
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	77,957	27,348	24	100,0	24	100,0	78,472	24,808
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	76,471	27,041	17	70,8	16	94,1	67,708	36,752
WEEK 13	Grade 1	31	96,9	30	96,8	65,556	30,929	23	95,8	22	95,7	67,424	30,201
WEEK 25	Grade 1	31	96,9	28	90,3	76,786	26,581	23	95,8	22	95,7	74,242	28,971
END OF TREATMENT	Grade 1	31	96,9	27	87,1	84,568	23,986	24	100,0	22	91,7	78,030	27,404
FU MONTH 18	Grade 1	30	93,8	27	90,0	84,568	23,986	23	95,8	22	95,7	76,515	20,993
FU MONTH 24	Grade 1	28	87,5	27	96,4	83,333	23,570	23	95,8	21	91,3	83,333	21,731
FU MONTH 36	Grade 1	27	84,4	26	96,3	84,615	29,410	22	91,7	20	90,9	80,833	27,718
BASELINE	Grade 2	552	100,0	536	97,1	81,561	21,796	557	100,0	542	97,3	79,859	23,996
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	76,320	24,192	446	80,1	424	95,1	75,393	24,091

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	75,137	25,185	524	94,1	504	96,2	73,148	25,089
WEEK 25	Grade 2	494	89,5	478	96,8	80,195	24,193	515	92,5	492	95,5	80,759	22,892
END OF TREATMENT	Grade 2	548	99,3	485	88,5	84,192	22,698	553	99,3	495	89,5	81,953	24,178
FU MONTH 18	Grade 2	507	91,8	456	89,9	87,756	20,656	517	92,8	447	86,5	84,303	22,273
FU MONTH 24	Grade 2	501	90,8	449	89,6	88,493	19,191	500	89,8	431	86,2	86,002	21,715
FU MONTH 36	Grade 2	487	88,2	437	89,7	89,550	18,858	476	85,5	414	87,0	87,238	21,359
BASELINE	Grade 3	1161	100,0	1130	97,3	80,973	23,888	1173	100,0	1141	97,3	80,879	23,936
END OF ANTHRACYCLINE	Grade 3	918	79,1	854	93,0	75,312	23,839	919	78,3	860	93,6	73,547	25,358
WEEK 13	Grade 3	1088	93,7	1029	94,6	72,352	25,789	1114	95,0	1053	94,5	73,124	26,019
WEEK 25	Grade 3	1059	91,2	1016	95,9	79,216	23,284	1087	92,7	1025	94,3	79,935	23,515
END OF TREATMENT	Grade 3	1150	99,1	998	86,8	83,768	21,254	1165	99,3	1048	90,0	83,572	22,433
FU MONTH 18	Grade 3	1067	91,9	945	88,6	85,732	21,193	1085	92,5	944	87,0	85,275	21,987
FU MONTH 24	Grade 3	1046	90,1	903	86,3	86,859	20,975	1053	89,8	916	87,0	87,518	20,603
FU MONTH 36	Grade 3	1002	86,3	876	87,4	88,204	19,511	999	85,2	866	86,7	87,991	20,700
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	82,275	22,375	69	100,0	68	98,6	78,676	26,367
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	80,556	27,361	64	92,8	62	96,9	75,806	25,191
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	72,131	28,983	64	92,8	60	93,8	75,833	23,253
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	82,471	23,863	63	91,3	62	98,4	84,409	20,215
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	82,514	26,602	69	100,0	60	87,0	85,000	20,970
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	86,111	26,253	63	91,3	58	92,1	84,770	21,694

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	87,346	24,430	62	89,9	56	90,3	87,798	19,460
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	88,782	22,800	59	85,5	51	86,4	85,948	23,658
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	704	96,7	84,044	22,088	715	100,0	685	95,8	82,871	24,001
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	545	92,1	76,911	23,101	572	80,0	523	91,4	75,175	25,172
WEEK 13	Breast conserving surgery	677	93,0	639	94,4	73,213	26,430	673	94,1	634	94,2	72,897	25,711
WEEK 25	Breast conserving surgery	665	91,3	637	95,8	80,037	24,417	654	91,5	614	93,9	80,646	23,810
END OF TREATMENT	Breast conserving surgery	722	99,2	623	86,3	84,296	22,344	711	99,4	622	87,5	83,789	23,212
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	87,262	20,838	659	92,2	557	84,5	85,996	22,000
FU MONTH 24	Breast conserving surgery	666	91,5	576	86,5	87,760	20,809	644	90,1	554	86,0	88,809	19,644
FU MONTH 36	Breast conserving surgery	651	89,4	562	86,3	88,998	19,578	616	86,2	535	86,9	89,283	19,763
BASELINE	Mastectomy	1083	100,0	1056	97,5	79,214	23,840	1107	100,0	1089	98,4	78,910	23,969
END OF ANTHRACYCLINE	Mastectomy	840	77,6	797	94,9	75,094	24,777	873	78,9	838	96,0	73,488	25,075
WEEK 13	Mastectomy	1011	93,4	967	95,6	72,958	25,500	1051	94,9	1004	95,5	73,290	25,687
WEEK 25	Mastectomy	980	90,5	943	96,2	79,286	23,099	1033	93,3	986	95,5	80,054	22,988
END OF TREATMENT	Mastectomy	1072	99,0	948	88,4	83,579	21,716	1099	99,3	1002	91,2	82,585	22,871
FU MONTH 18	Mastectomy	985	91,0	888	90,2	85,736	21,569	1028	92,9	913	88,8	84,118	22,082
FU MONTH 24	Mastectomy	967	89,3	857	88,6	87,028	20,507	993	89,7	869	87,5	85,846	21,625

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	88,299	19,722	939	84,8	816	86,9	86,458	21,924
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	644	97,6	81,392	23,370	665	100,0	641	96,4	81,357	24,358
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	481	92,7	76,057	24,276	523	78,6	493	94,3	72,752	25,506
WEEK 13	0 - < 2 cm	620	93,9	584	94,2	73,345	25,681	631	94,9	606	96,0	73,432	25,517
WEEK 25	0 - < 2 cm	608	92,1	580	95,4	80,489	23,078	617	92,8	588	95,3	81,774	22,054
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	84,115	22,086	661	99,4	597	90,3	83,724	22,432
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	87,286	20,486	624	93,8	558	89,4	85,364	21,968
FU MONTH 24	0 - < 2 cm	607	92,0	534	88,0	88,577	19,547	606	91,1	530	87,5	88,679	19,838
FU MONTH 36	0 - < 2 cm	596	90,3	525	88,1	89,651	19,202	580	87,2	507	87,4	89,250	19,993
BASELINE	>= 2 - < 5 cm	1009	100,0	977	96,8	81,610	22,738	991	100,0	969	97,8	80,014	23,731
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	753	94,5	76,073	23,548	789	79,6	743	94,2	74,652	24,939
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	73,389	25,504	940	94,9	891	94,8	72,503	25,800
WEEK 25	>= 2 - < 5 cm	910	90,2	879	96,6	79,370	23,726	919	92,7	866	94,2	79,061	24,223
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	867	86,9	84,237	21,555	985	99,4	875	88,8	83,124	22,697

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	828	89,7	86,171	21,128	914	92,2	781	85,4	84,315	22,530
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	86,369	21,387	889	89,7	776	87,3	85,868	21,686
FU MONTH 36	>= 2 - < 5 cm	857	84,9	762	88,9	87,883	20,031	839	84,7	727	86,7	86,107	22,207
BASELINE	>= 5 cm	139	100,0	137	98,6	76,521	26,162	165	100,0	163	98,8	80,061	24,064
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	73,016	27,579	132	80,0	124	93,9	77,151	24,368
WEEK 13	>= 5 cm	130	93,5	124	95,4	69,220	29,221	152	92,1	140	92,1	76,548	25,516
WEEK 25	>= 5 cm	124	89,2	118	95,2	76,554	25,620	150	90,9	145	96,7	81,954	22,004
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	80,000	24,041	163	98,8	151	92,6	80,684	25,898
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	82,866	25,947	148	89,7	130	87,8	85,897	19,408
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	87,688	20,190	141	85,5	116	82,3	87,787	19,332
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	88,284	19,227	135	81,8	115	85,2	90,145	17,646
BASELINE	Missing	3	100,0	2	66,7	91,667	11,785	2	100,0	2	100,0	33,333	47,140
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	77,778	9,623	2	100,0	2	100,0	50,000	23,570
WEEK 13	Missing	3	100,0	3	100,0	77,778	19,245	2	100,0	2	100,0	41,667	11,785
WEEK 25	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	50,000	23,570
END OF TREATMENT	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	33,333	47,140
FU MONTH 18	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	66,667	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	100,000	0,000	2	100,0	2	100,0	41,667	11,785
FU MONTH 36	Missing	3	100,0	3	100,0	88,889	19,245	2	100,0	2	100,0	50,000	23,570
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1319	97,9	81,905	22,785	1350	100,0	1311	97,1	80,981	23,896
END OF ANTHRACYCLINE	Yes	1103	81,9	1045	94,7	75,997	23,803	1104	81,8	1043	94,5	74,289	25,372
WEEK 13	Yes	1308	97,1	1244	95,1	72,776	26,034	1324	98,1	1251	94,5	73,181	25,403
WEEK 25	Yes	1277	94,8	1223	95,8	79,667	23,733	1302	96,4	1229	94,4	80,228	23,687

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1211	89,9	83,664	22,173	1350	100,0	1233	91,3	83,144	23,193
FU MONTH 18	Yes	1291	95,8	1143	88,5	86,177	21,440	1298	96,1	1129	87,0	85,016	22,162
FU MONTH 24	Yes	1266	94,0	1110	87,7	87,147	20,574	1260	93,3	1089	86,4	86,991	21,333
FU MONTH 36	Yes	1219	90,5	1062	87,1	88,293	19,764	1195	88,5	1035	86,6	87,713	20,955
BASELINE	No	464	100,0	441	95,0	78,874	24,547	473	100,0	464	98,1	78,951	24,444
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	75,253	25,228	342	72,3	319	93,3	73,720	24,298
WEEK 13	No	380	81,9	362	95,3	74,033	25,291	401	84,8	388	96,8	73,067	26,627
WEEK 25	No	368	79,3	357	97,0	79,318	23,325	386	81,6	372	96,4	80,466	21,975
END OF TREATMENT	No	447	96,3	360	80,5	84,537	21,260	461	97,5	392	85,0	82,781	22,405
FU MONTH 18	No	372	80,2	339	91,1	86,922	20,777	390	82,5	342	87,7	84,211	21,719
FU MONTH 24	No	367	79,1	323	88,0	87,926	20,820	378	79,9	335	88,6	87,065	19,521
FU MONTH 36	No	352	75,9	329	93,5	89,514	19,320	361	76,3	316	87,5	87,131	21,733
Race													
BASELINE	White	1252	100,0	1205	96,2	81,549	23,527	1255	100,0	1214	96,7	81,933	24,058
END OF ANTHRACYCLINE	White	1010	80,7	930	92,1	75,233	25,036	1018	81,1	941	92,4	74,407	25,370
WEEK 13	White	1158	92,5	1085	93,7	72,488	26,808	1183	94,3	1099	92,9	72,960	26,654
WEEK 25	White	1120	89,5	1061	94,7	79,485	24,595	1150	91,6	1071	93,1	80,859	23,644
END OF TREATMENT	White	1238	98,9	1046	84,5	83,636	23,256	1244	99,1	1086	87,3	82,965	24,221
FU MONTH 18	White	1138	90,9	979	86,0	86,568	21,981	1152	91,8	965	83,8	85,423	22,761
FU MONTH 24	White	1115	89,1	943	84,6	87,328	21,747	1120	89,2	939	83,8	87,593	21,053
FU MONTH 36	White	1071	85,5	923	86,2	88,118	21,008	1064	84,8	898	84,4	87,509	21,600
BASELINE	Black	25	100,0	24	96,0	85,417	21,032	31	100,0	30	96,8	62,222	34,722
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	79,630	21,695	15	48,4	15	100,0	53,333	28,312
WEEK 13	Black	21	84,0	17	81,0	67,647	28,547	29	93,5	28	96,6	60,714	33,090

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	18	85,7	82,407	21,747	29	93,5	28	96,6	67,857	31,404
END OF TREATMENT	Black	24	96,0	22	91,7	86,364	20,979	31	100,0	28	90,3	73,810	28,842
FU MONTH 18	Black	23	92,0	17	73,9	89,216	19,491	29	93,5	24	82,8	71,528	31,269
FU MONTH 24	Black	22	88,0	18	81,8	87,037	23,260	28	90,3	23	82,1	77,536	33,563
FU MONTH 36	Black	22	88,0	18	81,8	93,519	14,164	26	83,9	20	76,9	85,000	24,122
BASELINE	Asian	477	100,0	474	99,4	79,325	22,921	484	100,0	480	99,2	77,917	22,556
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	76,870	21,403	375	77,5	368	98,1	73,732	23,568
WEEK 13	Asian	455	95,4	450	98,9	74,000	23,450	466	96,3	465	99,8	74,516	21,828
WEEK 25	Asian	450	94,3	448	99,6	79,241	21,284	465	96,1	459	98,7	79,593	21,468
END OF TREATMENT	Asian	475	99,6	452	95,2	83,628	19,285	484	100,0	463	95,7	83,657	19,963
FU MONTH 18	Asian	447	93,7	433	96,9	85,373	19,781	461	95,2	441	95,7	84,051	19,914
FU MONTH 24	Asian	442	92,7	423	95,7	86,643	18,166	445	91,9	421	94,6	85,867	19,792
FU MONTH 36	Asian	424	88,9	401	94,6	88,986	16,622	425	87,8	398	93,6	87,437	20,521
BASELINE	Other	52	100,0	52	100,0	86,859	20,700	51	100,0	50	98,0	79,667	24,580
END OF ANTHRACYCLINE	Other	38	73,1	37	97,4	81,982	22,353	36	70,6	36	100,0	80,093	29,228
WEEK 13	Other	49	94,2	49	100,0	77,891	24,858	45	88,2	45	100,0	70,370	31,360
WEEK 25	Other	49	94,2	48	98,0	83,333	24,311	42	82,4	41	97,6	80,488	25,794
END OF TREATMENT	Other	52	100,0	47	90,4	89,362	16,457	50	98,0	47	94,0	84,397	16,812
FU MONTH 18	Other	50	96,2	48	96,0	89,583	21,089	44	86,3	39	88,6	86,325	18,682
FU MONTH 24	Other	49	94,2	45	91,8	94,074	15,953	43	84,3	39	90,7	90,171	19,010
FU MONTH 36	Other	49	94,2	44	89,8	92,045	18,499	39	76,5	33	84,6	91,919	12,584
BASELINE	Missing	5	100,0	5	100,0	76,667	19,003	2	100,0	1	50,0	83,333	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	60,000	43,461	2	100,0	2	100,0	83,333	23,570
WEEK 13	Missing	5	100,0	5	100,0	83,333	23,570	2	100,0	2	100,0	100,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	86,667	18,257	2	100,0	2	100,0	100,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	91,667	16,667	2	100,0	1	50,0	100,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	86,667	18,257	2	100,0	2	100,0	100,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	83,333	23,570	2	100,0	2	100,0	100,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	93,333	9,129	2	100,0	2	100,0	100,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC05_SG.xls
11AUG2020 15:55

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1759	97,1	9,602	10,910	1823	100,0	1773	97,3	10,285	11,285
END OF ANTHRACYCLINE	n/a	1432	79,1	1344	93,9	32,727	17,446	1446	79,3	1363	94,3	34,227	17,944
WEEK 13	n/a	1688	93,2	1607	95,2	30,279	17,861	1725	94,6	1636	94,8	31,416	18,492
WEEK 25	n/a	1645	90,8	1582	96,2	18,417	13,976	1688	92,6	1602	94,9	17,942	14,024
END OF TREATMENT	n/a	1794	99,1	1572	87,6	15,441	13,783	1811	99,3	1629	90,0	15,483	13,586
FU MONTH 18	n/a	1663	91,8	1483	89,2	13,776	12,478	1688	92,6	1473	87,3	15,123	13,163
FU MONTH 24	n/a	1633	90,2	1429	87,5	13,223	12,411	1638	89,9	1426	87,1	14,413	13,391
FU MONTH 36	n/a	1571	86,7	1389	88,4	13,385	13,021	1556	85,4	1349	86,7	14,671	14,308
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	5,831	8,816	43	100,0	40	93,0	10,476	12,066
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	33,513	17,073	26	60,5	25	96,2	34,508	17,017
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	34,758	17,559	40	93,0	39	97,5	32,947	18,200
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	17,110	12,856	38	88,4	35	92,1	18,186	17,058
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	12,951	9,166	42	97,7	37	88,1	14,178	12,756
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	12,255	9,949	39	90,7	35	89,7	14,150	13,142

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	11,979	12,456	39	90,7	34	87,2	14,426	14,943
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	11,355	13,156	39	90,7	37	94,9	15,444	14,907
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	252	98,1	9,743	10,587	278	100,0	271	97,5	10,241	11,200
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	178	95,2	32,211	16,942	203	73,0	191	94,1	36,865	19,733
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	28,296	17,402	263	94,6	253	96,2	33,791	17,328
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	17,280	13,326	256	92,1	247	96,5	18,559	13,658
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	226	89,0	14,100	12,480	276	99,3	255	92,4	16,421	14,935
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	12,841	13,231	259	93,2	232	89,6	15,935	14,293
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	208	85,2	12,221	11,952	256	92,1	230	89,8	14,462	14,418
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	213	89,9	12,797	13,536	251	90,3	226	90,0	14,272	14,580
BASELINE	1-3 positive nodes	907	100,0	885	97,6	9,466	10,692	900	100,0	875	97,2	10,133	11,343
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	663	93,0	32,842	18,079	707	78,6	668	94,5	34,007	17,874
WEEK 13	1-3 positive nodes	847	93,4	805	95,0	30,965	18,348	854	94,9	805	94,3	31,395	18,147
WEEK 25	1-3 positive nodes	825	91,0	784	95,0	18,380	14,474	836	92,9	790	94,5	17,660	13,413
END OF TREATMENT	1-3 positive nodes	899	99,1	781	86,9	15,876	14,172	897	99,7	813	90,6	15,344	13,324
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	13,745	12,318	852	94,7	743	87,2	15,059	12,983

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	726	87,8	13,715	12,801	830	92,2	726	87,5	14,453	12,799
FU MONTH 36	1-3 positive nodes	804	88,6	706	87,8	13,533	13,039	794	88,2	666	83,9	14,472	13,768
BASELINE	>= 4 positive nodes	596	100,0	573	96,1	10,073	11,486	602	100,0	587	97,5	10,520	11,207
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	32,710	16,788	510	84,7	479	93,9	33,468	17,289
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	29,735	17,244	568	94,4	539	94,9	30,221	19,461
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	19,104	13,577	558	92,7	530	95,0	18,059	14,871
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	15,582	14,027	596	99,0	524	87,9	15,336	13,373
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	14,383	12,565	538	89,4	463	86,1	14,894	12,887
FU MONTH 24	>= 4 positive nodes	516	86,6	452	87,6	13,012	11,967	513	85,2	436	85,0	14,319	13,710
FU MONTH 36	>= 4 positive nodes	484	81,2	426	88,0	13,643	12,730	472	78,4	420	89,0	15,134	14,969
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1401	97,4	9,352	10,644	1448	100,0	1409	97,3	9,931	10,934
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1342	93,9	32,741	17,454	1444	99,7	1362	94,3	34,214	17,944
WEEK 13	Anthracycline containing regimen	1347	93,6	1292	95,9	28,810	17,522	1374	94,9	1302	94,8	29,358	18,131
WEEK 25	Anthracycline containing regimen	1311	91,1	1256	95,8	17,860	13,801	1346	93,0	1277	94,9	17,111	13,876
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1258	88,0	15,342	13,763	1444	99,7	1304	90,3	15,199	13,601

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1182	88,9	13,729	12,278	1340	92,5	1179	88,0	14,950	13,135
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1144	87,6	13,216	12,350	1308	90,3	1137	86,9	14,338	13,545
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1108	88,0	13,240	12,811	1244	85,9	1084	87,1	14,449	14,419
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	10,579	11,858	375	100,0	364	97,1	11,656	12,472
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	23,810	6,734	2	0,5	1	50,0	52,381	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	36,301	18,004	351	93,6	334	95,2	39,438	17,706
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	20,562	14,452	342	91,2	325	95,0	21,208	14,149
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	314	86,0	15,838	13,880	367	97,9	325	88,6	16,624	13,487
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	13,963	13,254	348	92,8	294	84,5	15,821	13,277
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	285	87,2	13,253	12,674	330	88,0	289	87,6	14,706	12,782
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	281	90,1	13,957	13,824	312	83,2	265	84,9	15,580	13,835
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	841	97,3	9,755	10,882	858	100,0	837	97,6	10,399	11,200
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	638	94,9	32,954	17,315	661	77,0	622	94,1	35,205	18,407
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	29,733	17,721	804	93,7	773	96,1	32,072	18,246
WEEK 25	Negative (ER and PgR negative)	799	92,5	775	97,0	17,597	13,641	786	91,6	750	95,4	18,181	13,719
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	764	89,3	14,528	13,259	854	99,5	765	89,6	15,136	13,371
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	717	89,5	12,467	12,327	781	91,0	694	88,9	15,017	13,469
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	693	88,1	11,806	11,502	763	88,9	675	88,5	13,704	12,984
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	675	89,6	12,549	12,490	735	85,7	654	89,0	13,800	14,222
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	9,461	10,938	965	100,0	936	97,0	10,184	11,365
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	32,522	17,573	785	81,3	741	94,4	33,406	17,516
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	831	95,2	30,788	17,987	921	95,4	863	93,7	30,828	18,700
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	807	95,4	19,204	14,255	902	93,5	852	94,5	17,732	14,292
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	808	86,1	16,305	14,216	957	99,2	864	90,3	15,791	13,775
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	15,002	12,501	907	94,0	779	85,9	15,218	12,894
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	736	87,0	14,557	13,077	875	90,7	751	85,8	15,050	13,723

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	714	87,3	14,175	13,464	821	85,1	695	84,7	15,490	14,350
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	9,174	11,670	260	100,0	255	98,1	11,452	12,988
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	32,291	15,361	111	42,7	105	94,6	37,341	19,578
WEEK 13	USA/Canada	242	91,3	229	94,6	35,811	17,638	236	90,8	224	94,9	37,032	18,716
WEEK 25	USA/Canada	234	88,3	225	96,2	19,259	15,317	230	88,5	219	95,2	19,557	15,448
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	16,908	14,481	255	98,1	229	89,8	16,227	13,986
FU MONTH 18	USA/Canada	238	89,8	194	81,5	15,390	14,259	231	88,8	181	78,4	15,910	13,699
FU MONTH 24	USA/Canada	231	87,2	187	81,0	14,837	14,156	224	86,2	177	79,0	14,578	12,790
FU MONTH 36	USA/Canada	223	84,2	180	80,7	13,935	13,629	205	78,8	156	76,1	14,606	13,214
BASELINE	Western Europe	827	100,0	786	95,0	9,187	11,323	822	100,0	783	95,3	9,327	11,521
END OF ANTHRACYCLINE	Western Europe	732	88,5	666	91,0	34,993	17,825	728	88,6	664	91,2	36,129	18,303
WEEK 13	Western Europe	764	92,4	700	91,6	31,347	18,074	778	94,6	707	90,9	31,822	18,911
WEEK 25	Western Europe	738	89,2	690	93,5	19,582	14,395	750	91,2	681	90,8	18,280	13,762
END OF TREATMENT	Western Europe	821	99,3	691	84,2	17,542	15,128	817	99,4	704	86,2	16,627	14,299
FU MONTH 18	Western Europe	754	91,2	648	85,9	15,021	13,258	764	92,9	628	82,2	15,851	13,674
FU MONTH 24	Western Europe	739	89,4	611	82,7	14,500	12,880	747	90,9	621	83,1	15,474	14,227
FU MONTH 36	Western Europe	713	86,2	611	85,7	14,762	14,429	712	86,6	595	83,6	15,530	15,020
BASELINE	Asia Pacific	490	100,0	487	99,4	10,736	10,256	512	100,0	508	99,2	11,002	10,320
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	30,166	16,840	397	77,5	390	98,2	31,659	16,683
WEEK 13	Asia Pacific	466	95,1	465	99,8	28,295	16,971	493	96,3	492	99,8	29,509	16,585
WEEK 25	Asia Pacific	461	94,1	461	100,0	17,085	13,006	492	96,1	488	99,2	16,652	12,808

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	13,126	11,571	512	100,0	491	95,9	13,836	12,612
FU MONTH 18	Asia Pacific	459	93,7	451	98,3	11,823	10,425	485	94,7	473	97,5	13,823	12,128
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	11,163	10,764	470	91,8	447	95,1	12,956	12,292
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	11,928	10,809	453	88,5	432	95,4	13,161	13,152
BASELINE	Latin America	43	100,0	43	100,0	8,416	7,903	47	100,0	46	97,9	12,215	8,960
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	29,885	16,193	32	68,1	32	100,0	33,036	14,359
WEEK 13	Latin America	40	93,0	40	100,0	32,024	16,775	44	93,6	44	100,0	35,714	20,294
WEEK 25	Latin America	39	90,7	39	100,0	14,164	11,892	44	93,6	44	100,0	17,298	15,188
END OF TREATMENT	Latin America	42	97,7	38	90,5	9,211	7,202	45	95,7	42	93,3	14,966	11,879
FU MONTH 18	Latin America	41	95,3	37	90,2	9,867	9,219	42	89,4	40	95,2	14,524	11,810
FU MONTH 24	Latin America	40	93,0	36	90,0	8,730	11,355	41	87,2	39	95,1	10,358	10,436
FU MONTH 36	Latin America	38	88,4	34	89,5	11,064	11,227	37	78,7	36	97,3	12,698	10,495
BASELINE	Other	186	100,0	184	98,9	9,252	10,139	182	100,0	181	99,5	10,287	10,519
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	30,276	17,610	178	97,8	172	96,6	31,031	17,790
WEEK 13	Other	176	94,6	173	98,3	23,562	17,206	174	95,6	169	97,1	26,704	19,238
WEEK 25	Other	173	93,0	167	96,5	17,137	12,847	172	94,5	170	98,8	18,380	15,908
END OF TREATMENT	Other	185	99,5	162	87,6	12,610	11,838	182	100,0	163	89,6	14,597	12,649
FU MONTH 18	Other	171	91,9	153	89,5	13,160	12,017	166	91,2	151	91,0	15,389	13,641
FU MONTH 24	Other	169	90,9	154	91,1	13,147	11,963	156	85,7	142	91,0	15,269	13,917
FU MONTH 36	Other	160	86,0	146	91,3	11,657	11,588	149	81,9	130	87,2	16,380	16,361
Protocol version													
BASELINE	Protocol A	1240	100,0	1204	97,1	9,761	11,439	1246	100,0	1208	97,0	10,128	10,990

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	915	93,0	32,672	17,136	988	79,3	930	94,1	34,600	18,060
WEEK 13	Protocol A	1155	93,1	1109	96,0	30,132	17,826	1180	94,7	1112	94,2	31,883	18,675
WEEK 25	Protocol A	1125	90,7	1085	96,4	17,712	13,602	1157	92,9	1093	94,5	17,883	14,072
END OF TREATMENT	Protocol A	1229	99,1	1073	87,3	15,051	13,563	1236	99,2	1116	90,3	15,480	13,669
FU MONTH 18	Protocol A	1142	92,1	1024	89,7	13,690	12,562	1156	92,8	1005	86,9	15,048	13,288
FU MONTH 24	Protocol A	1124	90,6	992	88,3	13,265	12,586	1127	90,4	982	87,1	14,461	13,837
FU MONTH 36	Protocol A	1087	87,7	978	90,0	13,255	13,046	1069	85,8	933	87,3	14,617	14,418
BASELINE	Protocol Amendment B	571	100,0	555	97,2	9,258	9,663	577	100,0	565	97,9	10,622	11,893
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	429	95,8	32,845	18,107	458	79,4	433	94,5	33,427	17,686
WEEK 13	Protocol Amendment B	533	93,3	498	93,4	30,604	17,953	545	94,5	524	96,1	30,424	18,073
WEEK 25	Protocol Amendment B	520	91,1	497	95,6	19,957	14,657	531	92,0	509	95,9	18,070	13,933
END OF TREATMENT	Protocol Amendment B	565	98,9	499	88,3	16,280	14,222	575	99,7	513	89,2	15,491	13,419
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	13,969	12,298	532	92,2	468	88,0	15,284	12,905
FU MONTH 24	Protocol Amendment B	509	89,1	437	85,9	13,128	12,016	511	88,6	444	86,9	14,308	12,360
FU MONTH 36	Protocol Amendment B	484	84,8	411	84,9	13,693	12,971	487	84,4	416	85,4	14,793	14,075
Nodal status													
BASELINE	0 positive nodes	308	100,0	301	97,7	9,106	10,407	321	100,0	311	96,9	10,272	11,295
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	209	93,7	32,404	16,927	229	71,3	216	94,3	36,592	19,417
WEEK 13	0 positive nodes	294	95,5	279	94,9	29,315	17,554	303	94,4	292	96,4	33,679	17,417
WEEK 25	0 positive nodes	287	93,2	281	97,9	17,254	13,233	294	91,6	282	95,9	18,513	14,090
END OF TREATMENT	0 positive nodes	305	99,0	270	88,5	13,912	11,996	318	99,1	292	91,8	16,137	14,676
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	12,745	12,737	298	92,8	267	89,6	15,701	14,137

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	251	86,6	12,180	12,014	295	91,9	264	89,5	14,457	14,458
FU MONTH 36	0 positive nodes	283	91,9	257	90,8	12,550	13,457	290	90,3	263	90,7	14,437	14,604
BASELINE	>= 1 positive nodes	1503	100,0	1458	97,0	9,704	11,011	1502	100,0	1462	97,3	10,288	11,287
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	32,787	17,546	1217	81,0	1147	94,2	33,782	17,626
WEEK 13	>= 1 positive nodes	1394	92,7	1328	95,3	30,481	17,925	1422	94,7	1344	94,5	30,924	18,687
WEEK 25	>= 1 positive nodes	1358	90,4	1301	95,8	18,668	14,124	1394	92,8	1320	94,7	17,820	14,012
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1302	87,4	15,758	14,109	1493	99,4	1337	89,6	15,341	13,338
FU MONTH 18	>= 1 positive nodes	1371	91,2	1220	89,0	13,998	12,415	1390	92,5	1206	86,8	14,996	12,941
FU MONTH 24	>= 1 positive nodes	1343	89,4	1178	87,7	13,446	12,487	1343	89,4	1162	86,5	14,403	13,143
FU MONTH 36	>= 1 positive nodes	1288	85,7	1132	87,9	13,574	12,918	1266	84,3	1086	85,8	14,728	14,241
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	8,309	10,107	885	100,0	867	98,0	8,643	9,707
END OF ANTHRACYCLINE	Premenopausal	708	81,1	676	95,5	31,335	17,161	726	82,0	693	95,5	32,949	18,064
WEEK 13	Premenopausal	841	96,3	806	95,8	29,859	18,141	852	96,3	809	95,0	30,897	17,964
WEEK 25	Premenopausal	825	94,5	797	96,6	18,358	13,649	838	94,7	799	95,3	18,009	13,585
END OF TREATMENT	Premenopausal	866	99,2	764	88,2	15,199	13,110	881	99,5	812	92,2	14,944	13,056
FU MONTH 18	Premenopausal	819	93,8	722	88,2	13,400	12,123	835	94,4	738	88,4	14,383	12,164
FU MONTH 24	Premenopausal	803	92,0	704	87,7	12,926	12,036	807	91,2	708	87,7	13,660	12,662

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	672	87,8	12,978	12,824	773	87,3	667	86,3	13,615	13,267
BASELINE	Postmenopausal	933	100,0	901	96,6	10,864	11,497	929	100,0	898	96,7	11,841	12,382
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	663	92,2	34,224	17,645	711	76,5	663	93,2	35,532	17,639
WEEK 13	Postmenopausal	842	90,2	797	94,7	30,736	17,612	864	93,0	819	94,8	31,974	18,950
WEEK 25	Postmenopausal	815	87,4	780	95,7	18,530	14,322	841	90,5	796	94,6	17,931	14,468
END OF TREATMENT	Postmenopausal	923	98,9	804	87,1	15,689	14,426	921	99,1	809	87,8	16,029	14,088
FU MONTH 18	Postmenopausal	839	89,9	758	90,3	14,145	12,824	844	90,9	727	86,1	15,848	14,036
FU MONTH 24	Postmenopausal	825	88,4	721	87,4	13,521	12,797	823	88,6	712	86,5	15,113	13,947
FU MONTH 36	Postmenopausal	801	85,9	713	89,0	13,750	13,229	776	83,5	676	87,1	15,682	15,117
BASELINE	Unknown/Missing	5	100,0	5	100,0	2,857	6,389	9	100,0	8	88,9	13,690	16,581
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	22,540	11,399	9	100,0	7	77,8	37,245	27,240
WEEK 13	Unknown/Missing	5	100,0	4	80,0	23,810	3,888	9	100,0	8	88,9	26,766	23,704
WEEK 25	Unknown/Missing	5	100,0	5	100,0	10,159	9,823	9	100,0	7	77,8	11,565	12,251
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	11,905	4,762	9	100,0	8	88,9	15,079	14,197
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	11,111	5,499	9	100,0	8	88,9	17,560	17,586
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	11,905	4,762	8	88,9	6	75,0	20,159	24,134
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	16,667	6,148	7	77,8	6	85,7	18,254	24,359
Age II													
BASELINE	< 65	1581	100,0	1541	97,5	9,489	10,806	1604	100,0	1565	97,6	9,996	10,740
END OF ANTHRACYCLINE	< 65	1268	80,2	1197	94,4	32,346	17,223	1287	80,2	1221	94,9	33,937	17,859
WEEK 13	< 65	1497	94,7	1427	95,3	29,690	17,900	1529	95,3	1453	95,0	31,151	18,517

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1404	95,9	18,205	13,933	1501	93,6	1429	95,2	17,764	13,898
END OF TREATMENT	< 65	1569	99,2	1384	88,2	15,121	13,371	1596	99,5	1446	90,6	15,377	13,386
FU MONTH 18	< 65	1474	93,2	1312	89,0	13,517	12,357	1497	93,3	1317	88,0	14,970	13,028
FU MONTH 24	< 65	1446	91,5	1260	87,1	13,087	12,353	1450	90,4	1269	87,5	14,378	13,406
FU MONTH 36	< 65	1390	87,9	1231	88,6	13,160	12,800	1383	86,2	1202	86,9	14,689	14,267
BASELINE	>= 65	230	100,0	218	94,8	10,403	11,612	219	100,0	208	95,0	12,466	14,604
END OF ANTHRACYCLINE	>= 65	164	71,3	147	89,6	35,833	18,941	159	72,6	142	89,3	36,720	18,534
WEEK 13	>= 65	191	83,0	180	94,2	34,942	16,884	196	89,5	183	93,4	33,515	18,204
WEEK 25	>= 65	181	78,7	178	98,3	20,086	14,242	187	85,4	173	92,5	19,415	14,986
END OF TREATMENT	>= 65	225	97,8	188	83,6	17,798	16,355	215	98,2	183	85,1	16,326	15,093
FU MONTH 18	>= 65	189	82,2	171	90,5	15,762	13,235	191	87,2	156	81,7	16,423	14,231
FU MONTH 24	>= 65	187	81,3	169	90,4	14,242	12,821	188	85,8	157	83,5	14,696	13,307
FU MONTH 36	>= 65	181	78,7	158	87,3	15,137	14,549	173	79,0	147	85,0	14,523	14,685
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	11,674	15,101	24	100,0	24	100,0	11,310	10,584
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	33,987	17,827	17	70,8	16	94,1	34,226	18,005
WEEK 13	Grade 1	31	96,9	30	96,8	34,497	19,484	23	95,8	22	95,7	32,900	17,069
WEEK 25	Grade 1	31	96,9	29	93,5	18,391	13,750	23	95,8	22	95,7	21,429	14,076
END OF TREATMENT	Grade 1	31	96,9	27	87,1	15,873	13,141	24	100,0	22	91,7	16,017	14,736
FU MONTH 18	Grade 1	30	93,8	27	90,0	16,814	16,008	23	95,8	22	95,7	17,749	15,071
FU MONTH 24	Grade 1	28	87,5	27	96,4	15,697	12,792	23	95,8	21	91,3	15,420	16,489
FU MONTH 36	Grade 1	27	84,4	26	96,3	17,033	15,308	22	91,7	20	90,9	17,619	17,418
BASELINE	Grade 2	552	100,0	537	97,3	9,510	10,403	557	100,0	543	97,5	10,403	11,093
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	32,118	17,399	446	80,1	423	94,8	33,367	17,412

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	29,058	17,672	524	94,1	504	96,2	30,888	18,330
WEEK 25	Grade 2	494	89,5	477	96,6	17,504	13,408	515	92,5	493	95,7	17,103	13,624
END OF TREATMENT	Grade 2	548	99,3	485	88,5	15,068	14,210	553	99,3	496	89,7	14,847	13,523
FU MONTH 18	Grade 2	507	91,8	456	89,9	12,899	11,550	517	92,8	448	86,7	14,513	13,291
FU MONTH 24	Grade 2	501	90,8	448	89,4	12,509	11,733	500	89,8	432	86,4	14,436	13,565
FU MONTH 36	Grade 2	487	88,2	437	89,7	12,148	12,294	476	85,5	414	87,0	14,391	14,492
BASELINE	Grade 3	1161	100,0	1128	97,2	9,610	11,034	1173	100,0	1138	97,0	10,161	11,453
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	33,260	17,431	919	78,3	862	93,8	34,809	18,304
WEEK 13	Grade 3	1088	93,7	1030	94,7	30,884	18,058	1114	95,0	1050	94,3	31,696	18,706
WEEK 25	Grade 3	1059	91,2	1018	96,1	19,095	14,252	1087	92,7	1026	94,4	18,377	14,345
END OF TREATMENT	Grade 3	1150	99,1	999	86,9	15,715	13,656	1165	99,3	1051	90,2	15,823	13,731
FU MONTH 18	Grade 3	1067	91,9	946	88,7	14,073	12,603	1085	92,5	944	87,0	15,328	13,076
FU MONTH 24	Grade 3	1046	90,1	900	86,0	13,520	12,650	1053	89,8	917	87,1	14,460	13,377
FU MONTH 36	Grade 3	1002	86,3	874	87,2	13,905	13,114	999	85,2	864	86,5	14,745	14,081
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	9,221	10,644	69	100,0	68	98,6	11,064	10,323
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	28,158	17,677	64	92,8	62	96,9	32,002	16,371
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	27,700	14,318	64	92,8	60	93,8	30,397	16,752
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	14,039	12,847	63	91,3	61	96,8	16,146	11,163
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	13,739	12,780	69	100,0	60	87,0	14,590	10,964
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	14,462	15,395	63	91,3	59	93,7	15,496	12,954

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	12,963	13,608	62	89,9	56	90,3	13,095	11,056
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	13,217	15,449	59	85,5	51	86,4	14,535	15,566
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	703	96,6	9,488	11,158	715	100,0	683	95,5	10,338	11,988
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	546	92,2	34,119	17,744	572	80,0	522	91,3	36,291	17,971
WEEK 13	Breast conserving surgery	677	93,0	638	94,2	31,750	19,230	673	94,1	631	93,8	32,950	18,644
WEEK 25	Breast conserving surgery	665	91,3	636	95,6	19,390	14,838	654	91,5	614	93,9	19,208	14,699
END OF TREATMENT	Breast conserving surgery	722	99,2	623	86,3	16,851	15,020	711	99,4	621	87,3	17,090	14,818
FU MONTH 18	Breast conserving surgery	678	93,1	594	87,6	14,429	12,479	659	92,2	558	84,7	16,230	13,913
FU MONTH 24	Breast conserving surgery	666	91,5	573	86,0	14,410	13,450	644	90,1	555	86,2	15,610	13,903
FU MONTH 36	Breast conserving surgery	651	89,4	560	86,0	13,760	13,477	616	86,2	537	87,2	15,703	14,892
BASELINE	Mastectomy	1083	100,0	1056	97,5	9,678	10,746	1107	100,0	1089	98,4	10,232	10,809
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	31,776	17,184	873	78,9	840	96,2	32,969	17,817
WEEK 13	Mastectomy	1011	93,4	969	95,8	29,310	16,840	1051	94,9	1004	95,5	30,469	18,341
WEEK 25	Mastectomy	980	90,5	946	96,5	17,763	13,333	1033	93,3	987	95,5	17,158	13,542
END OF TREATMENT	Mastectomy	1072	99,0	949	88,5	14,516	12,831	1099	99,3	1007	91,6	14,504	12,678
FU MONTH 18	Mastectomy	985	91,0	889	90,3	13,340	12,465	1028	92,9	914	88,9	14,412	12,604
FU MONTH 24	Mastectomy	967	89,3	856	88,5	12,429	11,604	993	89,7	870	87,6	13,633	13,002

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	829	90,1	13,131	12,705	939	84,8	812	86,5	13,989	13,875
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	14,286	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	14,286	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	14,286	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	4,762	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	47,619	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	28,571	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	645	97,7	8,979	10,344	665	100,0	640	96,2	9,783	10,323
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	482	92,9	32,325	17,200	523	78,6	493	94,3	35,077	18,184
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	30,158	17,802	631	94,9	606	96,0	32,046	18,057
WEEK 25	0 - < 2 cm	608	92,1	580	95,4	18,317	14,139	617	92,8	588	95,3	17,993	13,798
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	15,199	13,314	661	99,4	599	90,6	15,180	12,597
FU MONTH 18	0 - < 2 cm	617	93,5	545	88,3	13,566	11,791	624	93,8	559	89,6	15,436	13,118
FU MONTH 24	0 - < 2 cm	607	92,0	531	87,5	12,970	11,762	606	91,1	531	87,6	14,786	13,289
FU MONTH 36	0 - < 2 cm	596	90,3	524	87,9	12,789	12,426	580	87,2	506	87,2	14,711	14,555
BASELINE	>= 2 - < 5 cm	1009	100,0	975	96,6	10,018	11,304	991	100,0	968	97,7	10,675	11,856
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	754	94,6	32,955	17,666	789	79,6	744	94,3	34,307	17,855
WEEK 13	>= 2 - < 5 cm	935	92,7	896	95,8	30,268	17,877	940	94,9	888	94,5	31,208	18,816
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	18,531	14,152	919	92,7	865	94,1	18,194	14,313
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	15,438	14,265	985	99,4	876	88,9	15,585	14,173

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	828	89,7	13,873	12,737	914	92,2	783	85,7	15,191	13,409
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	13,489	13,033	889	89,7	776	87,3	14,423	13,481
FU MONTH 36	>= 2 - < 5 cm	857	84,9	761	88,8	13,741	13,375	839	84,7	725	86,4	14,703	14,232
BASELINE	>= 5 cm	139	100,0	137	98,6	9,645	10,626	165	100,0	163	98,8	9,957	11,456
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	33,057	16,941	132	80,0	124	93,9	30,501	17,073
WEEK 13	>= 5 cm	130	93,5	125	96,2	30,886	18,111	152	92,1	140	92,1	29,874	18,365
WEEK 25	>= 5 cm	124	89,2	119	96,0	18,161	11,838	150	90,9	147	98,0	16,370	13,188
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	16,648	12,579	163	98,8	152	93,3	16,048	13,932
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	14,037	13,912	148	89,7	129	87,2	13,332	11,812
FU MONTH 24	>= 5 cm	118	84,9	110	93,2	12,691	10,942	141	85,5	117	83,0	12,655	13,321
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	13,763	13,415	135	81,8	116	85,9	14,306	13,910
BASELINE	Missing	3	100,0	2	66,7	4,762	6,734	2	100,0	2	100,0	9,524	6,734
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	28,571	26,513	2	100,0	2	100,0	26,190	30,305
WEEK 13	Missing	3	100,0	3	100,0	31,746	23,968	2	100,0	2	100,0	40,476	10,102
WEEK 25	Missing	3	100,0	3	100,0	14,286	14,286	2	100,0	2	100,0	9,524	13,469
END OF TREATMENT	Missing	3	100,0	3	100,0	12,698	10,997	2	100,0	2	100,0	19,048	20,203
FU MONTH 18	Missing	3	100,0	3	100,0	15,873	13,746	2	100,0	2	100,0	16,667	10,102
FU MONTH 24	Missing	3	100,0	3	100,0	7,937	9,913	2	100,0	2	100,0	14,286	6,734
FU MONTH 36	Missing	3	100,0	3	100,0	14,286	12,599	2	100,0	2	100,0	14,286	6,734
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1318	97,8	9,188	10,648	1350	100,0	1310	97,0	10,176	11,553
END OF ANTHRACYCLINE	Yes	1103	81,9	1047	94,9	32,802	17,268	1104	81,8	1044	94,6	34,240	17,860
WEEK 13	Yes	1308	97,1	1245	95,2	30,346	18,190	1324	98,1	1248	94,3	31,169	18,538
WEEK 25	Yes	1277	94,8	1224	95,8	18,563	13,885	1302	96,4	1229	94,4	17,985	14,201

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1211	89,9	15,698	13,968	1350	100,0	1236	91,6	15,387	13,564
FU MONTH 18	Yes	1291	95,8	1144	88,6	13,971	12,246	1298	96,1	1130	87,1	15,016	13,169
FU MONTH 24	Yes	1266	94,0	1107	87,4	13,469	12,428	1260	93,3	1092	86,7	14,561	13,431
FU MONTH 36	Yes	1219	90,5	1060	87,0	13,361	12,836	1195	88,5	1034	86,5	14,761	14,470
BASELINE	No	464	100,0	441	95,0	10,839	11,581	473	100,0	463	97,9	10,595	10,496
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	32,465	18,087	342	72,3	319	93,3	34,184	18,243
WEEK 13	No	380	81,9	362	95,3	30,047	16,703	401	84,8	388	96,8	32,210	18,343
WEEK 25	No	368	79,3	358	97,3	17,917	14,290	386	81,6	373	96,6	17,801	13,442
END OF TREATMENT	No	447	96,3	361	80,8	14,580	13,126	461	97,5	393	85,2	15,788	13,670
FU MONTH 18	No	372	80,2	339	91,1	13,120	13,229	390	82,5	343	87,9	15,479	13,158
FU MONTH 24	No	367	79,1	322	87,7	12,378	12,334	378	79,9	334	88,4	13,927	13,267
FU MONTH 36	No	352	75,9	329	93,5	13,460	13,617	361	76,3	315	87,3	14,376	13,781
Race													
BASELINE	White	1252	100,0	1203	96,1	8,953	10,868	1255	100,0	1212	96,6	9,730	11,377
END OF ANTHRACYCLINE	White	1010	80,7	932	92,3	33,666	17,423	1018	81,1	942	92,5	35,132	18,124
WEEK 13	White	1158	92,5	1086	93,8	30,587	18,034	1183	94,3	1096	92,6	31,671	18,830
WEEK 25	White	1120	89,5	1060	94,6	18,939	14,289	1150	91,6	1072	93,2	18,163	14,177
END OF TREATMENT	White	1238	98,9	1047	84,6	16,546	14,660	1244	99,1	1089	87,5	16,186	13,918
FU MONTH 18	White	1138	90,9	980	86,1	14,692	13,086	1152	91,8	964	83,7	15,697	13,536
FU MONTH 24	White	1115	89,1	939	84,2	14,050	12,787	1120	89,2	943	84,2	15,329	13,806
FU MONTH 36	White	1071	85,5	921	86,0	13,880	13,658	1064	84,8	896	84,2	15,448	14,886
BASELINE	Black	25	100,0	24	96,0	13,294	14,859	31	100,0	30	96,8	15,926	19,344
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	34,127	18,366	15	48,4	15	100,0	38,032	22,089
WEEK 13	Black	21	84,0	17	81,0	41,457	20,672	29	93,5	28	96,6	46,457	21,231

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	22,306	14,895	29	93,5	28	96,6	27,891	17,374
END OF TREATMENT	Black	24	96,0	22	91,7	16,450	12,532	31	100,0	28	90,3	23,356	20,383
FU MONTH 18	Black	23	92,0	17	73,9	16,527	14,592	29	93,5	24	82,8	23,148	13,815
FU MONTH 24	Black	22	88,0	18	81,8	12,963	11,411	28	90,3	23	82,1	15,217	14,044
FU MONTH 36	Black	22	88,0	18	81,8	15,079	13,394	26	83,9	20	76,9	20,476	20,676
BASELINE	Asian	477	100,0	475	99,6	11,096	10,883	484	100,0	480	99,2	11,247	10,378
END OF ANTHRACYCLINE	Asian	370	77,6	360	97,3	29,906	16,602	375	77,5	368	98,1	32,095	17,138
WEEK 13	Asian	455	95,4	450	98,9	28,966	17,375	466	96,3	465	99,8	29,756	16,812
WEEK 25	Asian	450	94,3	449	99,8	17,156	13,062	465	96,1	459	98,7	16,943	13,034
END OF TREATMENT	Asian	475	99,6	452	95,2	13,158	11,560	484	100,0	464	95,9	13,525	12,180
FU MONTH 18	Asian	447	93,7	433	96,9	11,919	10,820	461	95,2	444	96,3	13,618	12,133
FU MONTH 24	Asian	442	92,7	423	95,7	11,573	10,941	445	91,9	419	94,2	12,889	12,453
FU MONTH 36	Asian	424	88,9	402	94,8	12,232	11,027	425	87,8	398	93,6	12,940	12,586
BASELINE	Other	52	100,0	52	100,0	9,356	7,708	51	100,0	50	98,0	11,238	9,705
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	34,774	20,154	36	70,6	36	100,0	31,217	18,050
WEEK 13	Other	49	94,2	49	100,0	31,778	16,392	45	88,2	45	100,0	33,545	20,929
WEEK 25	Other	49	94,2	49	100,0	17,396	14,337	42	82,4	41	97,6	17,189	15,789
END OF TREATMENT	Other	52	100,0	47	90,4	12,614	10,968	50	98,0	47	94,0	14,083	11,010
FU MONTH 18	Other	50	96,2	48	96,0	10,714	10,648	44	86,3	39	88,6	13,919	12,184
FU MONTH 24	Other	49	94,2	45	91,8	11,605	16,141	43	84,3	39	90,7	8,893	9,493
FU MONTH 36	Other	49	94,2	43	87,8	12,957	15,494	39	76,5	33	84,6	11,544	10,650
BASELINE	Missing	5	100,0	5	100,0	8,571	16,633	2	100,0	1	50,0	4,762	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	42,857	35,635	2	100,0	2	100,0	26,190	16,836
WEEK 13	Missing	5	100,0	5	100,0	28,571	16,496	2	100,0	2	100,0	19,048	6,734

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	16,190	15,283	2	100,0	2	100,0	4,762	6,734
END OF TREATMENT	Missing	5	100,0	4	80,0	11,905	12,599	2	100,0	1	50,0	4,762	NE
FU MONTH 18	Missing	5	100,0	5	100,0	15,238	14,831	2	100,0	2	100,0	0,000	0,000
FU MONTH 24	Missing	5	100,0	4	80,0	13,095	12,524	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	12,381	15,649	2	100,0	2	100,0	4,762	6,734

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC10_SG.xls
11AUG2020 16:21

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1757	97,0	19,449	17,422	1823	100,0	1770	97,1	20,603	17,581
END OF ANTHRACYCLINE	n/a	1432	79,1	1345	93,9	14,298	14,702	1446	79,3	1361	94,1	14,503	14,536
WEEK 13	n/a	1688	93,2	1606	95,1	14,932	15,488	1725	94,6	1637	94,9	15,380	15,545
WEEK 25	n/a	1645	90,8	1580	96,0	22,161	19,125	1688	92,6	1602	94,9	19,711	17,868
END OF TREATMENT	n/a	1794	99,1	1571	87,6	17,763	16,876	1811	99,3	1619	89,4	16,423	16,874
FU MONTH 18	n/a	1663	91,8	1483	89,2	16,399	15,941	1688	92,6	1473	87,3	15,132	15,855
FU MONTH 24	n/a	1633	90,2	1432	87,7	13,573	15,168	1638	89,9	1424	86,9	13,298	14,853
FU MONTH 36	n/a	1571	86,7	1389	88,4	12,541	15,155	1556	85,4	1350	86,8	12,751	15,649
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	18,821	17,534	43	100,0	40	93,0	19,792	16,846
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	14,785	11,924	26	60,5	25	96,2	9,222	9,546
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	12,500	10,708	40	93,0	39	97,5	15,598	16,466
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	25,000	23,359	38	88,4	35	92,1	16,905	12,374
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	15,530	14,776	42	97,7	36	85,7	16,435	19,869
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	16,602	13,411	39	90,7	35	89,7	17,381	19,107

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	12,532	13,313	39	90,7	33	84,6	15,909	19,135
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	13,333	11,971	39	90,7	37	94,9	13,739	16,807
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	251	97,7	18,017	17,064	278	100,0	270	97,1	20,216	16,636
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	12,197	13,921	203	73,0	190	93,6	15,322	15,940
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	13,298	14,074	263	94,6	253	96,2	14,592	15,574
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	20,261	17,229	256	92,1	247	96,5	17,982	17,165
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	16,116	15,854	276	99,3	255	92,4	16,166	17,440
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	14,646	15,519	259	93,2	231	89,2	13,336	14,418
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	12,267	14,970	256	92,1	228	89,1	10,490	12,414
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	213	89,9	11,841	13,961	251	90,3	227	90,4	11,258	13,920
BASELINE	1-3 positive nodes	907	100,0	884	97,5	19,730	17,215	900	100,0	874	97,1	19,858	17,214
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	663	93,0	13,906	14,108	707	78,6	668	94,5	14,213	14,011
WEEK 13	1-3 positive nodes	847	93,4	804	94,9	14,918	15,809	854	94,9	806	94,4	14,968	15,377
WEEK 25	1-3 positive nodes	825	91,0	783	94,9	21,814	19,383	836	92,9	790	94,5	19,789	17,894
END OF TREATMENT	1-3 positive nodes	899	99,1	781	86,9	17,744	16,745	897	99,7	808	90,1	16,502	16,215
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	15,625	15,350	852	94,7	744	87,3	15,248	15,825

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	13,602	15,607	830	92,2	727	87,6	13,453	14,758
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	12,076	15,189	794	88,2	666	83,9	12,633	15,364
BASELINE	>= 4 positive nodes	596	100,0	573	96,1	19,697	17,892	602	100,0	586	97,3	21,947	18,534
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	15,613	15,845	510	84,7	478	93,7	14,859	14,856
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	15,891	15,882	568	94,4	539	94,9	16,352	15,708
WEEK 25	>= 4 positive nodes	533	89,4	516	96,8	23,326	19,130	558	92,7	530	95,0	20,587	18,416
END OF TREATMENT	>= 4 positive nodes	590	99,0	519	88,0	18,700	17,627	596	99,0	520	87,2	16,426	17,417
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	18,354	17,034	538	89,4	463	86,1	15,671	16,294
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	14,226	14,706	513	85,2	436	85,0	14,309	15,657
FU MONTH 36	>= 4 positive nodes	484	81,2	426	88,0	13,576	15,942	472	78,4	420	89,0	13,657	16,819
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1399	97,2	19,556	17,457	1448	100,0	1408	97,2	20,656	17,507
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1343	94,0	14,276	14,693	1444	99,7	1360	94,2	14,489	14,532
WEEK 13	Anthracycline containing regimen	1347	93,6	1293	96,0	14,997	15,482	1374	94,9	1302	94,8	15,515	15,659
WEEK 25	Anthracycline containing regimen	1311	91,1	1254	95,7	21,578	18,368	1346	93,0	1278	94,9	18,990	17,238
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	18,104	17,026	1444	99,7	1299	90,0	16,211	16,815

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1182	88,9	16,552	16,185	1340	92,5	1180	88,1	15,080	15,923
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1146	87,7	13,484	15,136	1308	90,3	1135	86,8	13,196	14,689
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1109	88,1	12,664	15,146	1244	85,9	1085	87,2	12,304	15,669
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	19,033	17,302	375	100,0	362	96,5	20,396	17,889
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	29,167	17,678	2	0,5	1	50,0	33,333	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	313	91,8	14,661	15,535	351	93,6	335	95,4	14,859	15,103
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	24,404	21,679	342	91,2	324	94,7	22,557	19,939
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	16,402	16,221	367	97,9	320	87,2	17,283	17,110
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	15,799	14,954	348	92,8	293	84,2	15,339	15,601
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	13,928	15,319	330	88,0	289	87,6	13,697	15,499
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	280	89,7	12,054	15,208	312	83,2	265	84,9	14,581	15,462
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	839	97,1	18,935	17,235	858	100,0	838	97,7	20,127	17,417
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	14,876	15,563	661	77,0	620	93,8	14,211	14,050
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	14,322	14,999	804	93,7	772	96,0	15,566	15,564
WEEK 25	Negative (ER and PgR negative)	799	92,5	773	96,7	21,579	18,361	786	91,6	751	95,5	18,871	17,030
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	17,136	16,308	854	99,5	762	89,2	16,222	16,647
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	717	89,5	15,411	15,588	781	91,0	692	88,6	14,824	15,092
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	694	88,2	12,732	14,816	763	88,9	673	88,2	12,403	13,491
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	676	89,8	11,744	14,151	735	85,7	654	89,0	12,398	14,944
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	19,920	17,587	965	100,0	932	96,6	21,030	17,725
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	13,775	13,866	785	81,3	741	94,4	14,747	14,935
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	830	95,1	15,502	15,919	921	95,4	865	93,9	15,215	15,535
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	807	95,4	22,718	19,824	902	93,5	851	94,3	20,453	18,555
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	808	86,1	18,355	17,385	957	99,2	857	89,6	16,602	17,081
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	17,323	16,220	907	94,0	781	86,1	15,404	16,506
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	14,363	15,461	875	90,7	751	85,8	14,100	15,942

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	713	87,2	13,297	16,023	821	85,1	696	84,8	13,083	16,286
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	20,206	18,373	260	100,0	254	97,7	21,402	19,322
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	10,294	14,371	111	42,7	105	94,6	12,090	14,612
WEEK 13	USA/Canada	242	91,3	229	94,6	11,196	14,878	236	90,8	224	94,9	11,657	14,653
WEEK 25	USA/Canada	234	88,3	224	95,7	22,842	20,708	230	88,5	219	95,2	20,282	18,666
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	16,242	16,844	255	98,1	228	89,4	14,267	16,244
FU MONTH 18	USA/Canada	238	89,8	194	81,5	13,688	14,615	231	88,8	181	78,4	14,104	16,536
FU MONTH 24	USA/Canada	231	87,2	188	81,4	14,007	17,137	224	86,2	177	79,0	10,782	13,276
FU MONTH 36	USA/Canada	223	84,2	180	80,7	11,667	15,574	205	78,8	155	75,6	11,129	14,254
BASELINE	Western Europe	827	100,0	785	94,9	21,607	18,534	822	100,0	781	95,0	22,300	18,681
END OF ANTHRACYCLINE	Western Europe	732	88,5	667	91,1	15,076	15,521	728	88,6	663	91,1	13,973	14,865
WEEK 13	Western Europe	764	92,4	700	91,6	16,579	16,949	778	94,6	709	91,1	15,903	16,413
WEEK 25	Western Europe	738	89,2	689	93,4	25,718	20,652	750	91,2	681	90,8	21,047	19,306
END OF TREATMENT	Western Europe	821	99,3	691	84,2	21,149	18,100	817	99,4	696	85,2	18,926	19,490
FU MONTH 18	Western Europe	754	91,2	647	85,8	19,702	17,406	764	92,9	627	82,1	17,402	18,122
FU MONTH 24	Western Europe	739	89,4	614	83,1	15,549	16,292	747	90,9	619	82,9	15,783	17,048
FU MONTH 36	Western Europe	713	86,2	610	85,6	14,854	16,451	712	86,6	596	83,7	15,194	17,763
BASELINE	Asia Pacific	490	100,0	487	99,4	16,809	14,191	512	100,0	507	99,0	19,001	14,921
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	15,196	13,823	397	77,5	390	98,2	15,897	13,419
WEEK 13	Asia Pacific	466	95,1	464	99,6	15,248	13,897	493	96,3	491	99,6	16,604	13,822
WEEK 25	Asia Pacific	461	94,1	461	100,0	18,721	15,558	492	96,1	488	99,2	18,630	15,142

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	15,607	15,007	512	100,0	490	95,7	15,272	13,368
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	14,307	14,406	485	94,7	473	97,5	13,460	12,523
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	11,640	13,101	470	91,8	447	95,1	11,838	12,219
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	11,184	13,995	453	88,5	432	95,4	11,304	13,607
BASELINE	Latin America	43	100,0	42	97,7	18,254	16,280	47	100,0	46	97,9	23,188	13,254
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	12,356	11,051	32	68,1	32	100,0	19,792	18,544
WEEK 13	Latin America	40	93,0	40	100,0	15,417	13,680	44	93,6	44	100,0	18,750	18,945
WEEK 25	Latin America	39	90,7	39	100,0	16,880	14,991	44	93,6	44	100,0	20,265	16,897
END OF TREATMENT	Latin America	42	97,7	38	90,5	14,254	15,966	45	95,7	42	93,3	17,659	14,975
FU MONTH 18	Latin America	41	95,3	37	90,2	11,486	10,458	42	89,4	40	95,2	14,583	13,176
FU MONTH 24	Latin America	40	93,0	36	90,0	11,111	12,117	41	87,2	39	95,1	14,103	14,453
FU MONTH 36	Latin America	38	88,4	34	89,5	8,824	10,648	37	78,7	36	97,3	11,574	12,798
BASELINE	Other	186	100,0	184	98,9	16,440	17,948	182	100,0	182	100,0	16,010	16,899
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	12,042	13,460	178	97,8	171	96,1	13,873	14,479
WEEK 13	Other	176	94,6	173	98,3	12,251	13,342	174	95,6	169	97,1	13,692	15,930
WEEK 25	Other	173	93,0	167	96,5	17,299	17,228	172	94,5	170	98,8	16,585	17,919
END OF TREATMENT	Other	185	99,5	162	87,6	12,346	13,783	182	100,0	163	89,6	11,895	13,780
FU MONTH 18	Other	171	91,9	153	89,5	13,235	13,870	166	91,2	152	91,6	12,336	13,731
FU MONTH 24	Other	169	90,9	153	90,5	11,256	13,036	156	85,7	142	91,0	9,977	12,286
FU MONTH 36	Other	160	86,0	147	91,9	8,730	11,220	149	81,9	131	87,9	8,651	11,983
Protocol version													
BASELINE	Protocol A	1240	100,0	1203	97,0	19,703	18,000	1246	100,0	1206	96,8	20,594	17,741

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	917	93,2	13,962	14,781	988	79,3	928	93,9	14,077	14,627
WEEK 13	Protocol A	1155	93,1	1107	95,8	14,305	15,446	1180	94,7	1113	94,3	15,059	15,601
WEEK 25	Protocol A	1125	90,7	1083	96,3	21,714	18,969	1157	92,9	1093	94,5	19,582	17,881
END OF TREATMENT	Protocol A	1229	99,1	1072	87,2	17,213	16,912	1236	99,2	1107	89,6	16,483	17,392
FU MONTH 18	Protocol A	1142	92,1	1024	89,7	15,807	15,831	1156	92,8	1003	86,8	14,767	15,880
FU MONTH 24	Protocol A	1124	90,6	995	88,5	13,074	15,117	1127	90,4	979	86,9	12,992	14,983
FU MONTH 36	Protocol A	1087	87,7	979	90,1	12,073	14,740	1069	85,8	932	87,2	12,172	15,339
BASELINE	Protocol Amendment B	571	100,0	554	97,0	18,898	16,098	577	100,0	564	97,7	20,622	17,248
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	15,018	14,520	458	79,4	433	94,5	15,416	14,311
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	16,322	15,506	545	94,5	524	96,1	16,062	15,417
WEEK 25	Protocol Amendment B	520	91,1	497	95,6	23,133	19,443	531	92,0	509	95,9	19,990	17,856
END OF TREATMENT	Protocol Amendment B	565	98,9	499	88,3	18,943	16,754	575	99,7	512	89,0	16,292	15,711
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	17,720	16,122	532	92,2	470	88,3	15,910	15,788
FU MONTH 24	Protocol Amendment B	509	89,1	437	85,9	14,709	15,241	511	88,6	445	87,1	13,970	14,558
FU MONTH 36	Protocol Amendment B	484	84,8	410	84,7	13,659	16,068	487	84,4	418	85,8	14,042	16,262
Nodal status													
BASELINE	0 positive nodes	308	100,0	300	97,4	18,148	17,115	321	100,0	310	96,6	20,161	16,636
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	12,579	13,649	229	71,3	215	93,9	14,612	15,442
WEEK 13	0 positive nodes	294	95,5	279	94,9	13,172	13,585	303	94,4	292	96,4	14,726	15,671
WEEK 25	0 positive nodes	287	93,2	281	97,9	20,987	18,331	294	91,6	282	95,9	17,849	16,631
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	16,021	15,659	318	99,1	291	91,5	16,199	17,721
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	14,966	15,188	298	92,8	266	89,3	13,868	15,138

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	252	86,9	12,313	14,675	295	91,9	261	88,5	11,175	13,523
FU MONTH 36	0 positive nodes	283	91,9	258	91,2	12,102	13,625	290	90,3	264	91,0	11,606	14,350
BASELINE	>= 1 positive nodes	1503	100,0	1457	96,9	19,717	17,479	1502	100,0	1460	97,2	20,696	17,779
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	14,616	14,872	1217	81,0	1146	94,2	14,483	14,366
WEEK 13	>= 1 positive nodes	1394	92,7	1327	95,2	15,302	15,839	1422	94,7	1345	94,6	15,523	15,519
WEEK 25	>= 1 positive nodes	1358	90,4	1299	95,7	22,415	19,290	1394	92,8	1320	94,7	20,109	18,103
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1300	87,3	18,126	17,102	1493	99,4	1328	88,9	16,472	16,689
FU MONTH 18	>= 1 positive nodes	1371	91,2	1220	89,0	16,708	16,088	1390	92,5	1207	86,8	15,410	16,001
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	13,842	15,264	1343	89,4	1163	86,6	13,774	15,100
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	12,641	15,487	1266	84,3	1086	85,8	13,029	15,942
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	19,125	17,097	885	100,0	865	97,7	20,328	17,446
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	14,025	14,193	726	82,0	692	95,3	14,708	14,110
WEEK 13	Premenopausal	841	96,3	806	95,8	15,502	15,583	852	96,3	809	95,0	15,956	15,675
WEEK 25	Premenopausal	825	94,5	796	96,5	22,808	19,012	838	94,7	800	95,5	19,712	18,239
END OF TREATMENT	Premenopausal	866	99,2	765	88,3	18,355	17,635	881	99,5	805	91,4	16,021	16,896
FU MONTH 18	Premenopausal	819	93,8	723	88,3	16,859	16,088	835	94,4	739	88,5	14,693	15,179
FU MONTH 24	Premenopausal	803	92,0	705	87,8	13,972	15,730	807	91,2	707	87,6	12,647	15,054

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	12,510	15,193	773	87,3	665	86,0	12,059	15,842
BASELINE	Postmenopausal	933	100,0	899	96,4	19,781	17,737	929	100,0	897	96,6	20,866	17,768
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	665	92,5	14,683	15,207	711	76,5	662	93,1	14,279	14,997
WEEK 13	Postmenopausal	842	90,2	796	94,5	14,357	15,405	864	93,0	820	94,9	14,831	15,408
WEEK 25	Postmenopausal	815	87,4	779	95,6	21,566	19,266	841	90,5	795	94,5	19,748	17,542
END OF TREATMENT	Postmenopausal	923	98,9	802	86,9	17,235	16,117	921	99,1	806	87,5	16,853	16,908
FU MONTH 18	Postmenopausal	839	89,9	757	90,2	15,936	15,799	844	90,9	726	86,0	15,607	16,547
FU MONTH 24	Postmenopausal	825	88,4	723	87,6	13,178	14,629	823	88,6	712	86,5	13,944	14,668
FU MONTH 36	Postmenopausal	801	85,9	712	88,9	12,605	15,156	776	83,5	679	87,5	13,480	15,480
BASELINE	Unknown/Missing	5	100,0	5	100,0	15,000	17,078	9	100,0	8	88,9	20,833	10,911
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	0,000	0,000	9	100,0	7	77,8	15,476	13,113
WEEK 13	Unknown/Missing	5	100,0	4	80,0	14,583	10,486	9	100,0	8	88,9	13,542	16,022
WEEK 25	Unknown/Missing	5	100,0	5	100,0	11,667	7,454	9	100,0	7	77,8	15,476	12,199
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	10,417	15,775	9	100,0	8	88,9	13,542	9,898
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	22,222	17,347	9	100,0	8	88,9	12,500	12,599
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	14,583	10,486	8	88,9	5	62,5	13,333	9,501
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	6,250	7,979	7	77,8	6	85,7	6,944	8,193
Age II													
BASELINE	< 65	1581	100,0	1539	97,3	19,302	17,160	1604	100,0	1563	97,4	20,745	17,740
END OF ANTHRACYCLINE	< 65	1268	80,2	1198	94,5	14,125	14,325	1287	80,2	1219	94,7	14,771	14,320
WEEK 13	< 65	1497	94,7	1428	95,4	15,161	15,293	1529	95,3	1453	95,0	15,816	15,697

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	22,337	19,251	1501	93,6	1430	95,3	19,899	17,997
END OF TREATMENT	< 65	1569	99,2	1383	88,1	18,055	17,015	1596	99,5	1437	90,0	16,535	16,755
FU MONTH 18	< 65	1474	93,2	1312	89,0	16,406	15,841	1497	93,3	1317	88,0	15,152	15,752
FU MONTH 24	< 65	1446	91,5	1262	87,3	13,642	15,177	1450	90,4	1268	87,4	13,146	14,798
FU MONTH 36	< 65	1390	87,9	1231	88,6	12,567	15,291	1383	86,2	1201	86,8	12,663	15,682
BASELINE	>= 65	230	100,0	218	94,8	20,489	19,185	219	100,0	207	94,5	19,525	16,326
END OF ANTHRACYCLINE	>= 65	164	71,3	147	89,6	15,703	17,462	159	72,6	142	89,3	12,207	16,146
WEEK 13	>= 65	191	83,0	178	93,2	13,093	16,909	196	89,5	184	93,9	11,941	13,846
WEEK 25	>= 65	181	78,7	177	97,8	20,763	18,087	187	85,4	172	92,0	18,152	16,727
END OF TREATMENT	>= 65	225	97,8	188	83,6	15,618	15,693	215	98,2	182	84,7	15,537	17,814
FU MONTH 18	>= 65	189	82,2	171	90,5	16,342	16,740	191	87,2	156	81,7	14,957	16,751
FU MONTH 24	>= 65	187	81,3	170	90,9	13,056	15,139	188	85,8	156	83,0	14,530	15,289
FU MONTH 36	>= 65	181	78,7	158	87,3	12,342	14,100	173	79,0	149	86,1	13,460	15,414
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	19,892	17,961	24	100,0	24	100,0	21,875	16,450
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	12,745	22,267	17	70,8	16	94,1	17,187	12,349
WEEK 13	Grade 1	31	96,9	30	96,8	16,111	19,070	23	95,8	22	95,7	20,455	14,256
WEEK 25	Grade 1	31	96,9	29	93,5	24,425	28,689	23	95,8	22	95,7	20,455	21,164
END OF TREATMENT	Grade 1	31	96,9	27	87,1	16,667	16,984	24	100,0	22	91,7	21,212	24,898
FU MONTH 18	Grade 1	30	93,8	26	86,7	13,996	12,558	23	95,8	22	95,7	20,455	17,952
FU MONTH 24	Grade 1	28	87,5	27	96,4	14,918	19,355	23	95,8	21	91,3	17,460	16,224
FU MONTH 36	Grade 1	27	84,4	26	96,3	15,064	23,096	22	91,7	20	90,9	14,583	16,857
BASELINE	Grade 2	552	100,0	534	96,7	18,321	17,375	557	100,0	540	96,9	19,630	16,712
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	14,079	14,109	446	80,1	423	94,8	14,762	14,527

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	14,358	14,813	524	94,1	504	96,2	15,592	15,555
WEEK 25	Grade 2	494	89,5	476	96,4	20,320	18,657	515	92,5	493	95,7	18,796	16,670
END OF TREATMENT	Grade 2	548	99,3	482	88,0	16,546	16,196	553	99,3	492	89,0	16,559	16,994
FU MONTH 18	Grade 2	507	91,8	457	90,1	15,092	14,769	517	92,8	448	86,7	15,718	15,890
FU MONTH 24	Grade 2	501	90,8	449	89,6	12,206	14,254	500	89,8	432	86,4	13,162	14,834
FU MONTH 36	Grade 2	487	88,2	437	89,7	11,092	14,015	476	85,5	415	87,2	12,517	15,679
BASELINE	Grade 3	1161	100,0	1129	97,2	20,148	17,504	1173	100,0	1138	97,0	20,943	17,973
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	14,320	14,497	919	78,3	860	93,6	14,276	14,649
WEEK 13	Grade 3	1088	93,7	1029	94,6	15,252	15,606	1114	95,0	1051	94,3	15,163	15,593
WEEK 25	Grade 3	1059	91,2	1017	96,0	23,208	19,098	1087	92,7	1025	94,3	20,255	18,524
END OF TREATMENT	Grade 3	1150	99,1	1001	87,0	18,445	17,154	1165	99,3	1046	89,8	16,268	16,747
FU MONTH 18	Grade 3	1067	91,9	946	88,7	17,186	16,420	1085	92,5	945	87,1	14,706	15,733
FU MONTH 24	Grade 3	1046	90,1	902	86,2	14,425	15,535	1053	89,8	916	87,0	13,291	14,923
FU MONTH 36	Grade 3	1002	86,3	874	87,2	13,088	15,076	999	85,2	864	86,5	12,928	15,704
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	16,270	15,513	69	100,0	68	98,6	22,181	18,075
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	16,377	19,777	64	92,8	62	96,9	15,188	13,708
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	13,525	16,953	64	92,8	60	93,8	15,556	15,069
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	17,768	15,986	63	91,3	62	98,4	17,742	14,432
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	16,667	17,280	69	100,0	59	85,5	16,243	14,551
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	14,815	17,782	63	91,3	58	92,1	15,517	16,626

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	10,031	12,888	62	89,9	55	88,7	12,879	13,401
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	14,263	19,757	59	85,5	51	86,4	10,948	14,190
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	702	96,4	19,729	17,234	715	100,0	682	95,4	20,463	17,323
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	547	92,4	13,467	14,593	572	80,0	522	91,3	12,963	13,467
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	14,386	15,043	673	94,1	632	93,9	13,933	15,425
WEEK 25	Breast conserving surgery	665	91,3	635	95,5	26,636	20,662	654	91,5	614	93,9	23,190	19,517
END OF TREATMENT	Breast conserving surgery	722	99,2	622	86,1	21,834	18,065	711	99,4	618	86,9	19,979	19,014
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	19,894	16,937	659	92,2	558	84,7	17,448	16,633
FU MONTH 24	Breast conserving surgery	666	91,5	575	86,3	16,425	16,147	644	90,1	556	86,3	14,593	15,470
FU MONTH 36	Breast conserving surgery	651	89,4	558	85,7	14,660	16,282	616	86,2	537	87,2	14,391	15,846
BASELINE	Mastectomy	1083	100,0	1055	97,4	19,263	17,552	1107	100,0	1087	98,2	20,686	17,755
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	14,867	14,758	873	78,9	838	96,0	15,450	15,097
WEEK 13	Mastectomy	1011	93,4	969	95,8	15,291	15,771	1051	94,9	1004	95,5	16,299	15,564
WEEK 25	Mastectomy	980	90,5	945	96,4	19,153	17,394	1033	93,3	987	95,5	17,533	16,405
END OF TREATMENT	Mastectomy	1072	99,0	949	88,5	15,095	15,488	1099	99,3	1000	91,0	14,225	15,007
FU MONTH 18	Mastectomy	985	91,0	890	90,4	14,070	14,799	1028	92,9	914	88,9	13,688	15,178
FU MONTH 24	Mastectomy	967	89,3	857	88,6	11,659	14,166	993	89,7	867	87,3	12,425	14,344

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	831	90,3	11,118	14,182	939	84,8	813	86,6	11,668	15,432
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	25,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	25,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	8,333	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	16,667	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	41,667	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	50,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	642	97,3	19,367	17,517	665	100,0	638	95,9	19,971	16,978
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	14,268	14,429	523	78,6	494	94,5	14,277	13,684
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	14,160	14,924	631	94,9	605	95,9	14,183	14,433
WEEK 25	0 - < 2 cm	608	92,1	579	95,2	22,275	18,968	617	92,8	588	95,3	20,550	19,034
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	18,499	16,849	661	99,4	596	90,2	16,392	16,957
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	16,702	15,042	624	93,8	558	89,4	15,402	16,196
FU MONTH 24	0 - < 2 cm	607	92,0	533	87,8	13,133	14,526	606	91,1	529	87,3	13,758	15,138
FU MONTH 36	0 - < 2 cm	596	90,3	526	88,3	12,643	14,681	580	87,2	506	87,2	12,445	14,527
BASELINE	>= 2 - < 5 cm	1009	100,0	976	96,7	19,362	17,268	991	100,0	968	97,7	21,244	18,281
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	754	94,6	13,911	14,352	789	79,6	742	94,0	14,870	15,244
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	15,043	15,158	940	94,9	890	94,7	15,952	16,180
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	22,033	19,268	919	92,7	865	94,1	19,454	17,346
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	16,916	16,392	985	99,4	870	88,3	16,580	16,832

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	829	89,8	15,859	16,104	914	92,2	784	85,8	14,948	15,756
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	13,783	15,206	889	89,7	776	87,3	13,230	14,822
FU MONTH 36	>= 2 - < 5 cm	857	84,9	759	88,6	12,381	15,386	839	84,7	726	86,5	12,760	16,068
BASELINE	>= 5 cm	139	100,0	137	98,6	20,560	18,192	165	100,0	162	98,2	19,204	15,450
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	17,302	17,982	132	80,0	123	93,2	13,234	13,571
WEEK 13	>= 5 cm	130	93,5	125	96,2	17,622	19,626	152	92,1	140	92,1	16,845	15,914
WEEK 25	>= 5 cm	124	89,2	118	95,2	22,622	19,170	150	90,9	147	98,0	17,630	15,682
END OF TREATMENT	>= 5 cm	138	99,3	124	89,9	20,228	19,885	163	98,8	151	92,6	15,471	16,855
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	19,029	18,789	148	89,7	129	87,2	14,922	14,975
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	14,339	17,914	141	85,5	117	83,0	11,467	13,567
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	12,926	15,857	135	81,8	116	85,9	13,386	16,216
BASELINE	Missing	3	100,0	2	66,7	12,500	17,678	2	100,0	2	100,0	25,000	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	11,111	12,729	2	100,0	2	100,0	12,500	5,893
WEEK 13	Missing	3	100,0	3	100,0	19,444	20,972	2	100,0	2	100,0	20,833	5,893
WEEK 25	Missing	3	100,0	3	100,0	19,444	9,623	2	100,0	2	100,0	37,500	29,463
END OF TREATMENT	Missing	3	100,0	3	100,0	19,444	17,347	2	100,0	2	100,0	29,167	17,678
FU MONTH 18	Missing	3	100,0	3	100,0	16,667	16,667	2	100,0	2	100,0	25,000	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	8,333	8,333	2	100,0	2	100,0	25,000	23,570
FU MONTH 36	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	50,000	58,926
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1316	97,7	19,472	17,043	1350	100,0	1306	96,7	20,680	17,675
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	14,157	14,729	1104	81,8	1042	94,4	13,862	14,088
WEEK 13	Yes	1308	97,1	1246	95,3	14,910	15,412	1324	98,1	1249	94,3	15,208	15,496
WEEK 25	Yes	1277	94,8	1222	95,7	24,077	19,665	1302	96,4	1229	94,4	20,968	18,382

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1210	89,8	19,557	17,450	1350	100,0	1228	91,0	17,465	17,446
FU MONTH 18	Yes	1291	95,8	1143	88,5	18,057	16,351	1298	96,1	1129	87,0	15,988	16,519
FU MONTH 24	Yes	1266	94,0	1109	87,6	14,828	15,690	1260	93,3	1092	86,7	14,166	15,407
FU MONTH 36	Yes	1219	90,5	1059	86,9	13,485	15,631	1195	88,5	1035	86,6	13,819	16,376
BASELINE	No	464	100,0	441	95,0	19,381	18,527	473	100,0	464	98,1	20,384	17,331
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	14,796	14,618	342	72,3	319	93,3	16,597	15,753
WEEK 13	No	380	81,9	360	94,7	15,008	15,769	401	84,8	388	96,8	15,936	15,708
WEEK 25	No	368	79,3	358	97,3	15,619	15,481	386	81,6	373	96,6	15,572	15,370
END OF TREATMENT	No	447	96,3	361	80,8	11,750	13,127	461	97,5	391	84,8	13,150	14,475
FU MONTH 18	No	372	80,2	340	91,4	10,825	13,034	390	82,5	344	88,2	12,322	13,079
FU MONTH 24	No	367	79,1	323	88,0	9,262	12,304	378	79,9	332	87,8	10,442	12,466
FU MONTH 36	No	352	75,9	330	93,8	9,512	13,085	361	76,3	315	87,3	9,242	12,362
Race													
BASELINE	White	1252	100,0	1203	96,1	20,181	18,231	1255	100,0	1209	96,3	21,126	18,287
END OF ANTHRACYCLINE	White	1010	80,7	932	92,3	13,829	14,990	1018	81,1	940	92,3	13,573	14,635
WEEK 13	White	1158	92,5	1086	93,8	14,638	16,139	1183	94,3	1097	92,7	14,421	15,701
WEEK 25	White	1120	89,5	1058	94,5	23,595	20,176	1150	91,6	1072	93,2	20,074	18,926
END OF TREATMENT	White	1238	98,9	1046	84,5	18,512	17,415	1244	99,1	1080	86,8	16,757	18,129
FU MONTH 18	White	1138	90,9	980	86,1	17,511	16,576	1152	91,8	964	83,7	15,690	17,029
FU MONTH 24	White	1115	89,1	942	84,5	14,316	15,614	1120	89,2	939	83,8	13,776	15,764
FU MONTH 36	White	1071	85,5	921	86,0	13,105	15,713	1064	84,8	897	84,3	13,356	16,609
BASELINE	Black	25	100,0	24	96,0	22,569	22,182	31	100,0	30	96,8	27,778	24,598
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	12,037	13,249	15	48,4	15	100,0	14,074	13,546
WEEK 13	Black	21	84,0	17	81,0	15,196	20,673	29	93,5	28	96,6	21,726	25,794

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	21,930	18,677	29	93,5	28	96,6	25,595	22,444
END OF TREATMENT	Black	24	96,0	22	91,7	21,212	26,443	31	100,0	28	90,3	21,131	22,622
FU MONTH 18	Black	23	92,0	17	73,9	10,784	11,698	29	93,5	24	82,8	26,042	21,041
FU MONTH 24	Black	22	88,0	18	81,8	12,037	23,260	28	90,3	23	82,1	17,754	17,643
FU MONTH 36	Black	22	88,0	18	81,8	8,333	15,914	26	83,9	20	76,9	22,083	24,073
BASELINE	Asian	477	100,0	474	99,4	17,352	14,710	484	100,0	480	99,2	18,819	15,087
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	15,697	13,841	375	77,5	368	98,1	16,629	13,752
WEEK 13	Asian	455	95,4	449	98,7	15,794	13,954	466	96,3	465	99,8	17,115	13,882
WEEK 25	Asian	450	94,3	449	99,8	19,024	15,910	465	96,1	459	98,7	18,464	14,785
END OF TREATMENT	Asian	475	99,6	452	95,2	16,040	14,700	484	100,0	463	95,7	15,371	13,277
FU MONTH 18	Asian	447	93,7	434	97,1	14,363	14,433	461	95,2	444	96,3	13,507	12,505
FU MONTH 24	Asian	442	92,7	423	95,7	12,116	13,472	445	91,9	421	94,6	11,896	12,354
FU MONTH 36	Asian	424	88,9	402	94,8	11,629	13,952	425	87,8	398	93,6	11,160	12,653
BASELINE	Other	52	100,0	51	98,1	19,172	16,323	51	100,0	50	98,0	20,833	16,170
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	12,719	13,245	36	70,6	36	100,0	17,824	17,834
WEEK 13	Other	49	94,2	49	100,0	13,095	12,148	45	88,2	45	100,0	17,407	17,662
WEEK 25	Other	49	94,2	49	100,0	19,898	20,114	42	82,4	41	97,6	21,138	16,677
END OF TREATMENT	Other	52	100,0	47	90,4	15,071	16,267	50	98,0	47	94,0	16,135	14,371
FU MONTH 18	Other	50	96,2	48	96,0	13,542	14,344	44	86,3	39	88,6	13,675	13,174
FU MONTH 24	Other	49	94,2	45	91,8	12,037	15,946	43	84,3	39	90,7	14,957	14,456
FU MONTH 36	Other	49	94,2	43	87,8	10,078	11,863	39	76,5	33	84,6	10,606	12,547
BASELINE	Missing	5	100,0	5	100,0	30,000	27,386	2	100,0	1	50,0	16,667	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	16,667	28,868	2	100,0	2	100,0	4,167	5,893
WEEK 13	Missing	5	100,0	5	100,0	18,333	12,360	2	100,0	2	100,0	4,167	5,893

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	23,333	18,066	2	100,0	2	100,0	0,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	29,167	30,807	2	100,0	1	50,0	25,000	NE
FU MONTH 18	Missing	5	100,0	4	80,0	22,917	21,916	2	100,0	2	100,0	4,167	5,893
FU MONTH 24	Missing	5	100,0	4	80,0	16,667	20,412	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	18,333	22,361	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC11_SG.xls
11AUG2020 16:23

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1757	97,0	23,013	18,901	1823	100,0	1771	97,1	23,317	19,409
END OF ANTHRACYCLINE	n/a	1432	79,1	1345	93,9	16,084	17,600	1446	79,3	1362	94,2	16,858	17,510
WEEK 13	n/a	1688	93,2	1606	95,1	18,310	18,892	1725	94,6	1636	94,8	20,976	20,245
WEEK 25	n/a	1645	90,8	1580	96,0	20,299	19,461	1688	92,6	1602	94,9	20,478	19,397
END OF TREATMENT	n/a	1794	99,1	1571	87,6	18,990	19,691	1811	99,3	1619	89,4	19,532	20,286
FU MONTH 18	n/a	1663	91,8	1483	89,2	18,693	19,805	1688	92,6	1473	87,3	19,405	20,626
FU MONTH 24	n/a	1633	90,2	1431	87,6	17,952	19,876	1638	89,9	1424	86,9	18,239	19,934
FU MONTH 36	n/a	1571	86,7	1389	88,4	16,739	19,408	1556	85,4	1350	86,8	17,761	19,915
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	17,347	23,778	43	100,0	40	93,0	15,278	19,602
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	7,885	9,598	26	60,5	25	96,2	11,556	17,996
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	10,101	12,864	40	93,0	39	97,5	15,100	17,750
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	18,217	17,624	38	88,4	35	92,1	14,921	13,459
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	44	86,3	13,636	18,540	42	97,7	36	85,7	11,728	18,391
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	11,886	15,600	39	90,7	35	89,7	11,746	18,066

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	10,582	13,872	39	90,7	33	84,6	13,468	23,200
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	45	97,8	10,617	14,006	39	90,7	37	94,9	10,210	16,642
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	251	97,7	16,180	16,541	278	100,0	269	96,8	18,298	18,973
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	179	95,7	12,849	15,881	203	73,0	190	93,6	14,269	17,081
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	235	94,8	13,995	17,690	263	94,6	253	96,2	17,523	19,063
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	14,986	17,768	256	92,1	247	96,5	17,364	19,404
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	227	89,4	12,775	16,901	276	99,3	255	92,4	15,534	19,356
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	220	89,4	13,939	18,631	259	93,2	231	89,2	14,719	18,340
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	209	85,7	13,025	18,455	256	92,1	228	89,1	13,060	16,507
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	213	89,9	11,972	16,736	251	90,3	227	90,4	12,677	18,366
BASELINE	1-3 positive nodes	907	100,0	884	97,5	23,221	18,591	900	100,0	875	97,2	23,067	18,954
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	663	93,0	15,309	16,606	707	78,6	668	94,5	16,592	17,395
WEEK 13	1-3 positive nodes	847	93,4	804	94,9	18,443	18,765	854	94,9	806	94,4	21,085	20,586
WEEK 25	1-3 positive nodes	825	91,0	783	94,9	19,711	19,233	836	92,9	790	94,5	20,190	18,578
END OF TREATMENT	1-3 positive nodes	899	99,1	781	86,9	18,224	19,249	897	99,7	808	90,1	19,417	19,572
FU MONTH 18	1-3 positive nodes	838	92,4	736	87,8	17,271	19,222	852	94,7	744	87,3	19,556	21,005

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	727	87,9	17,989	19,774	830	92,2	727	87,6	18,096	19,947
FU MONTH 36	1-3 positive nodes	804	88,6	705	87,7	16,627	19,589	794	88,2	666	83,9	18,335	19,646
BASELINE	>= 4 positive nodes	596	100,0	573	96,1	26,168	19,048	602	100,0	587	97,5	26,538	19,632
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	472	95,2	18,938	19,435	510	84,7	479	93,9	18,534	17,665
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	20,735	19,542	568	94,4	538	94,7	22,862	20,202
WEEK 25	>= 4 positive nodes	533	89,4	516	96,8	23,816	20,065	558	92,7	530	95,0	22,725	20,626
END OF TREATMENT	>= 4 positive nodes	590	99,0	519	88,0	23,314	20,620	596	99,0	520	87,2	22,212	21,492
FU MONTH 18	>= 4 positive nodes	533	89,4	484	90,8	23,623	20,514	538	89,4	463	86,1	22,078	20,780
FU MONTH 24	>= 4 positive nodes	516	86,6	453	87,8	20,849	20,566	513	85,2	436	85,0	21,547	20,672
FU MONTH 36	>= 4 positive nodes	484	81,2	426	88,0	19,953	20,218	472	78,4	420	89,0	20,265	20,804
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1399	97,2	23,255	18,824	1448	100,0	1408	97,2	23,331	19,284
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1343	94,0	16,083	17,601	1444	99,7	1361	94,3	16,871	17,510
WEEK 13	Anthracycline containing regimen	1347	93,6	1293	96,0	18,282	18,705	1374	94,9	1302	94,8	20,460	19,780
WEEK 25	Anthracycline containing regimen	1311	91,1	1254	95,7	20,091	19,284	1346	93,0	1278	94,9	19,453	18,909
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1256	87,9	18,825	19,435	1444	99,7	1299	90,0	19,070	20,041

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1182	88,9	18,415	19,585	1340	92,5	1180	88,1	18,997	20,133
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1145	87,7	17,860	20,038	1308	90,3	1135	86,8	18,155	20,016
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1109	88,1	16,451	19,259	1244	85,9	1085	87,2	17,384	19,847
BASELINE	Non-anthracycline containing regimen	372	100,0	358	96,2	22,067	19,195	375	100,0	363	96,8	23,263	19,914
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	16,667	23,570	2	0,5	1	50,0	0,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	313	91,8	18,424	19,676	351	93,6	334	95,2	22,987	21,881
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	21,097	20,139	342	91,2	324	94,7	24,520	20,756
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	315	86,3	19,647	20,702	367	97,9	320	87,2	21,406	21,184
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	301	90,1	19,786	20,643	348	92,8	293	84,2	21,047	22,466
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	286	87,5	18,318	19,244	330	88,0	289	87,6	18,570	19,639
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	280	89,7	17,877	19,983	312	83,2	265	84,9	19,308	20,159
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	839	97,1	21,918	19,097	858	100,0	837	97,6	22,216	18,823
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	639	95,1	15,980	18,293	661	77,0	620	93,8	16,362	17,472
WEEK 13	Negative (ER and PgR negative)	815	94,3	776	95,2	18,270	19,257	804	93,7	772	96,0	20,366	20,213
WEEK 25	Negative (ER and PgR negative)	799	92,5	773	96,7	19,915	19,373	786	91,6	751	95,5	20,003	19,700
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	18,334	19,405	854	99,5	762	89,2	18,241	19,784
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	717	89,5	17,511	19,490	781	91,0	692	88,6	18,216	19,723
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	693	88,1	16,819	19,222	763	88,9	673	88,2	16,568	18,290
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	676	89,8	15,639	18,695	735	85,7	654	89,0	15,834	18,872
BASELINE	Positive (ER and/or PgR positive)	947	100,0	918	96,9	24,014	18,674	965	100,0	934	96,8	24,304	19,878
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	706	92,9	16,179	16,960	785	81,3	742	94,5	17,273	17,542
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	830	95,1	18,347	18,557	921	95,4	864	93,8	21,521	20,271
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	807	95,4	20,666	19,550	902	93,5	851	94,3	20,897	19,128
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	808	86,1	19,609	19,951	957	99,2	857	89,6	20,679	20,667
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	766	88,9	19,800	20,044	907	94,0	781	86,1	20,458	21,352
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	738	87,2	19,015	20,427	875	90,7	751	85,8	19,737	21,200

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	713	87,2	17,781	20,018	821	85,1	696	84,8	19,572	20,699
Geographical region II													
BASELINE	USA/Canada	265	100,0	259	97,7	23,316	20,841	260	100,0	254	97,7	24,453	21,012
END OF ANTHRACYCLINE	USA/Canada	109	41,1	102	93,6	11,111	15,557	111	42,7	105	94,6	16,190	17,229
WEEK 13	USA/Canada	242	91,3	229	94,6	15,575	19,483	236	90,8	224	94,9	20,833	22,028
WEEK 25	USA/Canada	234	88,3	224	95,7	19,742	18,982	230	88,5	219	95,2	21,664	20,394
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	18,390	21,035	255	98,1	228	89,4	17,690	20,899
FU MONTH 18	USA/Canada	238	89,8	194	81,5	18,786	21,924	231	88,8	181	78,4	21,670	25,209
FU MONTH 24	USA/Canada	231	87,2	188	81,4	16,874	19,580	224	86,2	177	79,0	16,604	18,933
FU MONTH 36	USA/Canada	223	84,2	180	80,7	16,173	19,488	205	78,8	155	75,6	17,348	19,701
BASELINE	Western Europe	827	100,0	785	94,9	22,512	19,409	822	100,0	782	95,1	22,457	20,389
END OF ANTHRACYCLINE	Western Europe	732	88,5	667	91,1	15,192	17,921	728	88,6	663	91,1	14,572	17,499
WEEK 13	Western Europe	764	92,4	700	91,6	17,992	19,336	778	94,6	708	91,0	19,609	21,030
WEEK 25	Western Europe	738	89,2	689	93,4	20,376	20,549	750	91,2	681	90,8	19,424	19,783
END OF TREATMENT	Western Europe	821	99,3	691	84,2	19,633	20,251	817	99,4	696	85,2	20,131	21,970
FU MONTH 18	Western Europe	754	91,2	647	85,8	20,385	21,958	764	92,9	627	82,1	20,459	22,353
FU MONTH 24	Western Europe	739	89,4	613	82,9	19,929	21,894	747	90,9	619	82,9	19,781	22,232
FU MONTH 36	Western Europe	713	86,2	610	85,6	17,969	20,740	712	86,6	596	83,7	19,687	21,791
BASELINE	Asia Pacific	490	100,0	487	99,4	23,865	17,700	512	100,0	507	99,0	23,384	17,390
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	374	98,2	18,419	17,146	397	77,5	390	98,2	19,174	16,440
WEEK 13	Asia Pacific	466	95,1	464	99,6	20,402	18,384	493	96,3	491	99,6	22,788	18,604
WEEK 25	Asia Pacific	461	94,1	461	100,0	20,969	18,837	492	96,1	488	99,2	20,811	17,673

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	19,241	19,567	512	100,0	490	95,7	19,059	17,811
FU MONTH 18	Asia Pacific	459	93,7	452	98,5	17,416	16,846	485	94,7	473	97,5	16,866	15,681
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	16,049	17,718	470	91,8	447	95,1	16,480	16,684
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	15,869	18,033	453	88,5	432	95,4	15,021	16,553
BASELINE	Latin America	43	100,0	42	97,7	19,577	15,484	47	100,0	46	97,9	27,053	17,475
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	11,877	13,586	32	68,1	32	100,0	18,750	17,497
WEEK 13	Latin America	40	93,0	40	100,0	14,444	15,347	44	93,6	44	100,0	19,949	20,970
WEEK 25	Latin America	39	90,7	39	100,0	17,664	16,065	44	93,6	44	100,0	18,939	17,376
END OF TREATMENT	Latin America	42	97,7	38	90,5	16,374	15,225	45	95,7	42	93,3	18,519	19,581
FU MONTH 18	Latin America	41	95,3	37	90,2	10,511	11,986	42	89,4	40	95,2	14,444	17,103
FU MONTH 24	Latin America	40	93,0	36	90,0	12,963	17,110	41	87,2	39	95,1	13,390	12,272
FU MONTH 36	Latin America	38	88,4	34	89,5	9,150	16,744	37	78,7	36	97,3	13,580	13,042
BASELINE	Other	186	100,0	184	98,9	23,249	17,605	182	100,0	182	100,0	24,298	18,498
END OF ANTHRACYCLINE	Other	181	97,3	173	95,6	18,112	18,177	178	97,8	172	96,6	20,478	18,900
WEEK 13	Other	176	94,6	173	98,3	18,497	17,863	174	95,6	169	97,1	21,893	18,522
WEEK 25	Other	173	93,0	167	96,5	19,494	17,944	172	94,5	170	98,8	22,614	21,551
END OF TREATMENT	Other	185	99,5	162	87,6	16,941	16,439	182	100,0	163	89,6	21,234	19,045
FU MONTH 18	Other	171	91,9	153	89,5	17,175	15,911	166	91,2	152	91,6	21,564	20,786
FU MONTH 24	Other	169	90,9	153	90,5	18,010	17,476	156	85,7	142	91,0	20,423	20,992
FU MONTH 36	Other	160	86,0	147	91,9	16,553	17,514	149	81,9	131	87,9	19,678	21,859
Protocol version													
BASELINE	Protocol A	1240	100,0	1203	97,0	22,412	18,975	1246	100,0	1205	96,7	23,038	19,477

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	917	93,2	15,176	17,358	988	79,3	929	94,0	16,296	17,080
WEEK 13	Protocol A	1155	93,1	1107	95,8	17,199	18,469	1180	94,7	1112	94,2	20,359	20,190
WEEK 25	Protocol A	1125	90,7	1083	96,3	19,334	19,156	1157	92,9	1093	94,5	20,052	19,201
END OF TREATMENT	Protocol A	1229	99,1	1072	87,2	18,294	20,085	1236	99,2	1107	89,6	19,116	20,555
FU MONTH 18	Protocol A	1142	92,1	1024	89,7	17,855	19,294	1156	92,8	1003	86,8	18,987	20,020
FU MONTH 24	Protocol A	1124	90,6	994	88,4	17,259	19,856	1127	90,4	979	86,9	17,688	19,600
FU MONTH 36	Protocol A	1087	87,7	979	90,1	16,133	19,324	1069	85,8	932	87,2	17,096	19,789
BASELINE	Protocol Amendment B	571	100,0	554	97,0	24,318	18,689	577	100,0	566	98,1	23,910	19,267
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	428	95,5	18,030	17,973	458	79,4	433	94,5	18,065	18,359
WEEK 13	Protocol Amendment B	533	93,3	499	93,6	20,775	19,593	545	94,5	524	96,1	22,286	20,319
WEEK 25	Protocol Amendment B	520	91,1	497	95,6	22,401	19,968	531	92,0	509	95,9	21,393	19,800
END OF TREATMENT	Protocol Amendment B	565	98,9	499	88,3	20,485	18,751	575	99,7	512	89,0	20,432	19,682
FU MONTH 18	Protocol Amendment B	521	91,2	459	88,1	20,564	20,800	532	92,2	470	88,3	20,296	21,859
FU MONTH 24	Protocol Amendment B	509	89,1	437	85,9	19,527	19,855	511	88,6	445	87,1	19,451	20,621
FU MONTH 36	Protocol Amendment B	484	84,8	410	84,7	18,184	19,555	487	84,4	418	85,8	19,245	20,139
Nodal status													
BASELINE	0 positive nodes	308	100,0	300	97,4	16,370	17,880	321	100,0	309	96,3	17,907	19,050
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	210	94,2	12,116	15,203	229	71,3	215	93,9	13,953	17,168
WEEK 13	0 positive nodes	294	95,5	279	94,9	13,381	17,060	303	94,4	292	96,4	17,199	18,881
WEEK 25	0 positive nodes	287	93,2	281	97,9	15,480	17,753	294	91,6	282	95,9	17,061	18,767
END OF TREATMENT	0 positive nodes	305	99,0	271	88,9	12,915	17,145	318	99,1	291	91,5	15,063	19,250
FU MONTH 18	0 positive nodes	292	94,8	263	90,1	13,604	18,159	298	92,8	266	89,3	14,327	18,298

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	251	86,6	12,616	17,769	295	91,9	261	88,5	13,112	17,440
FU MONTH 36	0 positive nodes	283	91,9	258	91,2	11,736	16,276	290	90,3	264	91,0	12,332	18,125
BASELINE	>= 1 positive nodes	1503	100,0	1457	96,9	24,380	18,821	1502	100,0	1462	97,3	24,460	19,297
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1135	93,9	16,818	17,918	1217	81,0	1147	94,2	17,403	17,527
WEEK 13	>= 1 positive nodes	1394	92,7	1327	95,2	19,346	19,100	1422	94,7	1344	94,5	21,796	20,444
WEEK 25	>= 1 positive nodes	1358	90,4	1299	95,7	21,341	19,663	1394	92,8	1320	94,7	21,208	19,458
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1300	87,3	20,256	19,956	1493	99,4	1328	88,9	20,511	20,383
FU MONTH 18	>= 1 positive nodes	1371	91,2	1220	89,0	19,791	19,980	1390	92,5	1207	86,8	20,524	20,947
FU MONTH 24	>= 1 positive nodes	1343	89,4	1180	87,9	19,087	20,122	1343	89,4	1163	86,6	19,390	20,282
FU MONTH 36	>= 1 positive nodes	1288	85,7	1131	87,8	17,880	19,885	1266	84,3	1086	85,8	19,081	20,114
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	853	97,7	24,254	19,137	885	100,0	866	97,9	23,820	19,287
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	16,354	17,146	726	82,0	693	95,5	16,859	17,172
WEEK 13	Premenopausal	841	96,3	806	95,8	18,838	18,570	852	96,3	809	95,0	21,082	19,710
WEEK 25	Premenopausal	825	94,5	796	96,5	20,840	19,155	838	94,7	800	95,5	20,181	18,471
END OF TREATMENT	Premenopausal	866	99,2	765	88,3	18,911	19,205	881	99,5	805	91,4	19,400	19,919
FU MONTH 18	Premenopausal	819	93,8	723	88,3	17,981	19,696	835	94,4	739	88,5	18,283	19,815
FU MONTH 24	Premenopausal	803	92,0	705	87,8	17,431	19,476	807	91,2	707	87,6	17,020	19,534

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	673	88,0	16,675	19,820	773	87,3	665	86,0	17,377	19,387
BASELINE	Postmenopausal	933	100,0	899	96,4	21,864	18,639	929	100,0	897	96,6	22,829	19,573
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	665	92,5	15,881	18,088	711	76,5	662	93,1	16,918	17,929
WEEK 13	Postmenopausal	842	90,2	796	94,5	17,783	19,237	864	93,0	819	94,8	20,845	20,777
WEEK 25	Postmenopausal	815	87,4	779	95,6	19,805	19,807	841	90,5	795	94,5	20,748	20,317
END OF TREATMENT	Postmenopausal	923	98,9	802	86,9	19,050	20,157	921	99,1	806	87,5	19,665	20,641
FU MONTH 18	Postmenopausal	839	89,9	757	90,2	19,360	19,928	844	90,9	726	86,0	20,531	21,376
FU MONTH 24	Postmenopausal	825	88,4	722	87,5	18,421	20,297	823	88,6	712	86,5	19,421	20,256
FU MONTH 36	Postmenopausal	801	85,9	712	88,9	16,815	19,067	776	83,5	679	87,5	18,229	20,473
BASELINE	Unknown/Missing	5	100,0	5	100,0	17,778	12,669	9	100,0	8	88,9	23,611	13,849
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	6,667	9,938	9	100,0	7	77,8	11,111	9,072
WEEK 13	Unknown/Missing	5	100,0	4	80,0	16,667	14,344	9	100,0	8	88,9	23,611	20,945
WEEK 25	Unknown/Missing	5	100,0	5	100,0	11,111	7,857	9	100,0	7	77,8	23,810	17,484
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	22,222	22,222	9	100,0	8	88,9	19,444	23,570
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	22,222	11,111	9	100,0	8	88,9	20,833	21,771
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	25,000	10,638	8	88,9	5	62,5	22,222	23,570
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	13,889	10,638	7	77,8	6	85,7	7,407	9,072
Age II													
BASELINE	< 65	1581	100,0	1539	97,3	23,612	18,874	1604	100,0	1563	97,4	23,818	19,461
END OF ANTHRACYCLINE	< 65	1268	80,2	1198	94,5	16,212	17,593	1287	80,2	1220	94,8	16,981	17,007
WEEK 13	< 65	1497	94,7	1428	95,4	18,546	18,806	1529	95,3	1453	95,0	21,496	20,186

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1403	95,8	20,650	19,359	1501	93,6	1430	95,3	20,886	19,267
END OF TREATMENT	< 65	1569	99,2	1383	88,1	19,230	19,518	1596	99,5	1437	90,0	19,558	20,239
FU MONTH 18	< 65	1474	93,2	1312	89,0	18,801	19,845	1497	93,3	1317	88,0	19,261	20,490
FU MONTH 24	< 65	1446	91,5	1262	87,3	18,005	19,786	1450	90,4	1268	87,4	18,187	19,728
FU MONTH 36	< 65	1390	87,9	1231	88,6	16,856	19,533	1383	86,2	1201	86,8	17,920	19,950
BASELINE	>= 65	230	100,0	218	94,8	18,782	18,589	219	100,0	208	95,0	19,551	18,631
END OF ANTHRACYCLINE	>= 65	164	71,3	147	89,6	15,042	17,679	159	72,6	142	89,3	15,806	21,392
WEEK 13	>= 65	191	83,0	178	93,2	16,417	19,522	196	89,5	183	93,4	16,849	20,299
WEEK 25	>= 65	181	78,7	177	97,8	17,514	20,087	187	85,4	172	92,0	17,087	20,188
END OF TREATMENT	>= 65	225	97,8	188	83,6	17,228	20,894	215	98,2	182	84,7	19,322	20,711
FU MONTH 18	>= 65	189	82,2	171	90,5	17,869	19,531	191	87,2	156	81,7	20,620	21,770
FU MONTH 24	>= 65	187	81,3	169	90,4	17,554	20,595	188	85,8	156	83,0	18,661	21,604
FU MONTH 36	>= 65	181	78,7	158	87,3	15,823	18,444	173	79,0	149	86,1	16,480	19,657
Histological grade													
BASELINE	Grade 1	32	100,0	31	96,9	21,147	19,533	24	100,0	24	100,0	21,296	18,798
END OF ANTHRACYCLINE	Grade 1	18	56,3	17	94,4	15,686	20,435	17	70,8	16	94,1	18,056	20,235
WEEK 13	Grade 1	31	96,9	30	96,8	23,333	26,156	23	95,8	22	95,7	21,717	20,992
WEEK 25	Grade 1	31	96,9	29	93,5	21,073	26,947	23	95,8	22	95,7	23,737	14,667
END OF TREATMENT	Grade 1	31	96,9	27	87,1	13,992	21,702	24	100,0	22	91,7	19,192	18,523
FU MONTH 18	Grade 1	30	93,8	26	86,7	16,239	19,432	23	95,8	22	95,7	25,253	20,909
FU MONTH 24	Grade 1	28	87,5	27	96,4	18,519	20,901	23	95,8	21	91,3	18,519	20,588
FU MONTH 36	Grade 1	27	84,4	26	96,3	22,222	29,648	22	91,7	20	90,9	16,944	16,270
BASELINE	Grade 2	552	100,0	534	96,7	23,117	18,120	557	100,0	541	97,1	22,448	18,793
END OF ANTHRACYCLINE	Grade 2	445	80,6	424	95,3	16,208	17,339	446	80,1	423	94,8	17,021	17,115

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	486	95,9	19,159	18,898	524	94,1	504	96,2	21,010	19,359
WEEK 25	Grade 2	494	89,5	476	96,4	19,713	18,918	515	92,5	493	95,7	20,171	18,971
END OF TREATMENT	Grade 2	548	99,3	482	88,0	18,568	19,902	553	99,3	492	89,0	19,151	18,955
FU MONTH 18	Grade 2	507	91,8	457	90,1	16,971	19,272	517	92,8	448	86,7	19,246	20,928
FU MONTH 24	Grade 2	501	90,8	449	89,6	17,001	19,496	500	89,8	432	86,4	17,438	18,353
FU MONTH 36	Grade 2	487	88,2	437	89,7	15,205	18,431	476	85,5	415	87,2	17,912	21,600
BASELINE	Grade 3	1161	100,0	1129	97,2	23,059	19,153	1173	100,0	1138	97,0	23,828	19,772
END OF ANTHRACYCLINE	Grade 3	918	79,1	856	93,2	15,972	17,707	919	78,3	861	93,7	16,654	17,719
WEEK 13	Grade 3	1088	93,7	1029	94,6	17,833	18,584	1114	95,0	1050	94,3	20,926	20,651
WEEK 25	Grade 3	1059	91,2	1017	96,0	20,802	19,662	1087	92,7	1025	94,3	20,602	19,889
END OF TREATMENT	Grade 3	1150	99,1	1001	87,0	19,453	19,486	1165	99,3	1046	89,8	19,572	20,908
FU MONTH 18	Grade 3	1067	91,9	946	88,7	19,673	20,093	1085	92,5	945	87,1	19,300	20,619
FU MONTH 24	Grade 3	1046	90,1	901	86,1	18,646	20,132	1053	89,8	916	87,0	18,711	20,853
FU MONTH 36	Grade 3	1002	86,3	874	87,2	17,449	19,475	999	85,2	864	86,5	17,638	19,149
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	22,222	20,835	69	100,0	68	98,6	22,386	18,362
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	17,130	17,449	64	92,8	62	96,9	18,280	16,844
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	17,122	19,728	64	92,8	60	93,8	21,296	20,589
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	15,900	15,310	63	91,3	62	98,4	19,713	15,895
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	16,940	20,448	69	100,0	59	85,5	22,128	20,748
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	17,284	18,651	63	91,3	58	92,1	20,115	18,317

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	13,992	17,823	62	89,9	55	88,7	16,566	15,695
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	14,957	19,418	59	85,5	51	86,4	18,954	20,159
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	702	96,4	19,745	18,227	715	100,0	683	95,5	19,904	19,578
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	547	92,4	14,158	16,787	572	80,0	522	91,3	14,442	17,220
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	16,928	18,413	673	94,1	631	93,8	18,348	19,791
WEEK 25	Breast conserving surgery	665	91,3	635	95,5	18,819	19,589	654	91,5	614	93,9	19,354	19,558
END OF TREATMENT	Breast conserving surgery	722	99,2	622	86,1	19,034	20,296	711	99,4	618	86,9	19,786	21,036
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	18,887	20,581	659	92,2	558	84,7	20,181	23,023
FU MONTH 24	Breast conserving surgery	666	91,5	574	86,2	18,051	20,708	644	90,1	556	86,3	18,625	20,751
FU MONTH 36	Breast conserving surgery	651	89,4	558	85,7	16,477	19,791	616	86,2	537	87,2	17,639	19,682
BASELINE	Mastectomy	1083	100,0	1055	97,4	25,187	19,036	1107	100,0	1087	98,2	25,432	18,987
END OF ANTHRACYCLINE	Mastectomy	840	77,6	798	95,0	17,405	18,027	873	78,9	839	96,1	18,302	17,461
WEEK 13	Mastectomy	1011	93,4	969	95,8	19,218	19,156	1051	94,9	1004	95,5	22,615	20,370
WEEK 25	Mastectomy	980	90,5	945	96,4	21,293	19,321	1033	93,3	987	95,5	21,164	19,279
END OF TREATMENT	Mastectomy	1072	99,0	949	88,5	18,961	19,296	1099	99,3	1000	91,0	19,328	19,772
FU MONTH 18	Mastectomy	985	91,0	890	90,4	18,564	19,281	1028	92,9	914	88,9	18,891	18,986
FU MONTH 24	Mastectomy	967	89,3	857	88,6	17,885	19,311	993	89,7	867	87,3	17,948	19,370

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	831	90,3	16,914	19,157	939	84,8	813	86,6	17,842	20,080
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	55,556	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	55,556	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	55,556	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	642	97,3	22,222	18,838	665	100,0	638	95,9	21,256	18,644
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	483	93,1	14,504	16,440	523	78,6	494	94,5	16,622	17,646
WEEK 13	0 - < 2 cm	620	93,9	583	94,0	17,219	18,561	631	94,9	605	95,9	18,935	19,045
WEEK 25	0 - < 2 cm	608	92,1	579	95,2	19,564	18,983	617	92,8	588	95,3	19,180	18,361
END OF TREATMENT	0 - < 2 cm	655	99,2	576	87,9	17,998	19,875	661	99,4	596	90,2	17,785	19,277
FU MONTH 18	0 - < 2 cm	617	93,5	544	88,2	17,596	19,515	624	93,8	558	89,4	18,369	20,950
FU MONTH 24	0 - < 2 cm	607	92,0	532	87,6	16,896	19,135	606	91,1	529	87,3	17,265	20,371
FU MONTH 36	0 - < 2 cm	596	90,3	526	88,3	15,811	18,619	580	87,2	506	87,2	16,140	19,449
BASELINE	>= 2 - < 5 cm	1009	100,0	976	96,7	22,928	18,615	991	100,0	969	97,8	24,366	20,008
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	754	94,6	16,674	17,711	789	79,6	742	94,0	17,273	17,561
WEEK 13	>= 2 - < 5 cm	935	92,7	895	95,7	18,461	18,590	940	94,9	889	94,6	22,216	20,931
WEEK 25	>= 2 - < 5 cm	910	90,2	880	96,7	20,316	19,997	919	92,7	865	94,1	21,252	20,103
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	868	87,0	18,747	18,746	985	99,4	870	88,3	20,262	20,740

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	829	89,8	18,630	19,704	914	92,2	784	85,8	19,983	20,610
FU MONTH 24	>= 2 - < 5 cm	905	89,7	785	86,7	18,061	20,013	889	89,7	776	87,3	18,986	19,997
FU MONTH 36	>= 2 - < 5 cm	857	84,9	759	88,6	16,733	19,227	839	84,7	726	86,5	18,748	20,096
BASELINE	>= 5 cm	139	100,0	137	98,6	27,413	20,702	165	100,0	162	98,2	25,240	18,202
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	105	92,9	19,471	21,171	132	80,0	124	93,9	15,323	16,800
WEEK 13	>= 5 cm	130	93,5	125	96,2	22,489	22,018	152	92,1	140	92,1	21,905	20,429
WEEK 25	>= 5 cm	124	89,2	118	95,2	24,011	17,491	150	90,9	147	98,0	21,088	19,012
END OF TREATMENT	>= 5 cm	138	99,3	124	89,9	25,045	23,882	163	98,8	151	92,6	22,185	21,233
FU MONTH 18	>= 5 cm	120	86,3	107	89,2	24,663	21,233	148	89,7	129	87,2	20,500	19,367
FU MONTH 24	>= 5 cm	118	84,9	111	94,1	22,322	21,994	141	85,5	117	83,0	17,616	17,421
FU MONTH 36	>= 5 cm	115	82,7	101	87,8	21,342	23,814	135	81,8	116	85,9	18,582	20,450
BASELINE	Missing	3	100,0	2	66,7	16,667	23,570	2	100,0	2	100,0	16,667	7,857
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	3,704	6,415	2	100,0	2	100,0	16,667	7,857
WEEK 13	Missing	3	100,0	3	100,0	11,111	11,111	2	100,0	2	100,0	22,222	0,000
WEEK 25	Missing	3	100,0	3	100,0	11,111	11,111	2	100,0	2	100,0	22,222	31,427
END OF TREATMENT	Missing	3	100,0	3	100,0	29,630	25,660	2	100,0	2	100,0	22,222	0,000
FU MONTH 18	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	11,111	0,000
FU MONTH 24	Missing	3	100,0	3	100,0	14,815	16,973	2	100,0	2	100,0	22,222	15,713
FU MONTH 36	Missing	3	100,0	3	100,0	25,926	23,130	2	100,0	2	100,0	22,222	31,427
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1316	97,7	22,919	18,846	1350	100,0	1308	96,9	23,008	19,457
END OF ANTHRACYCLINE	Yes	1103	81,9	1048	95,0	15,659	17,613	1104	81,8	1043	94,5	16,219	17,261
WEEK 13	Yes	1308	97,1	1246	95,3	18,169	18,827	1324	98,1	1248	94,3	20,419	20,002
WEEK 25	Yes	1277	94,8	1222	95,7	20,599	19,478	1302	96,4	1229	94,4	20,486	19,555

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1210	89,8	20,041	20,112	1350	100,0	1228	91,0	20,033	20,466
FU MONTH 18	Yes	1291	95,8	1143	88,5	19,899	20,242	1298	96,1	1129	87,0	20,190	21,370
FU MONTH 24	Yes	1266	94,0	1108	87,5	18,803	20,091	1260	93,3	1092	86,7	19,216	20,368
FU MONTH 36	Yes	1219	90,5	1059	86,9	17,191	19,677	1195	88,5	1035	86,6	18,594	20,340
BASELINE	No	464	100,0	441	95,0	23,293	19,081	473	100,0	463	97,9	24,190	19,269
END OF ANTHRACYCLINE	No	329	70,9	297	90,3	17,583	17,500	342	72,3	319	93,3	18,948	18,169
WEEK 13	No	380	81,9	360	94,7	18,796	19,135	401	84,8	388	96,8	22,766	20,937
WEEK 25	No	368	79,3	358	97,3	19,274	19,395	386	81,6	373	96,6	20,450	18,895
END OF TREATMENT	No	447	96,3	361	80,8	15,466	17,789	461	97,5	391	84,8	17,960	19,656
FU MONTH 18	No	372	80,2	340	91,4	14,641	17,694	390	82,5	344	88,2	16,828	17,756
FU MONTH 24	No	367	79,1	323	88,0	15,033	18,860	378	79,9	332	87,8	15,027	18,094
FU MONTH 36	No	352	75,9	330	93,8	15,286	18,473	361	76,3	315	87,3	15,026	18,215
Race													
BASELINE	White	1252	100,0	1203	96,1	22,726	19,772	1255	100,0	1210	96,4	22,870	19,797
END OF ANTHRACYCLINE	White	1010	80,7	932	92,3	14,944	17,710	1018	81,1	941	92,4	15,356	17,508
WEEK 13	White	1158	92,5	1086	93,8	17,255	18,824	1183	94,3	1096	92,6	19,358	20,233
WEEK 25	White	1120	89,5	1058	94,5	19,833	19,987	1150	91,6	1072	93,2	19,875	19,797
END OF TREATMENT	White	1238	98,9	1046	84,5	18,494	19,764	1244	99,1	1080	86,8	19,630	21,305
FU MONTH 18	White	1138	90,9	980	86,1	19,121	20,908	1152	91,8	964	83,7	20,228	21,978
FU MONTH 24	White	1115	89,1	941	84,4	18,715	20,720	1120	89,2	939	83,8	19,152	21,440
FU MONTH 36	White	1071	85,5	921	86,0	17,330	20,200	1064	84,8	897	84,3	18,903	21,231
BASELINE	Black	25	100,0	24	96,0	17,593	17,619	31	100,0	30	96,8	33,704	30,110
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	14,815	15,713	15	48,4	15	100,0	19,259	17,042
WEEK 13	Black	21	84,0	17	81,0	19,608	26,214	29	93,5	28	96,6	34,524	25,898

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	21,053	16,099	29	93,5	28	96,6	31,349	24,013
END OF TREATMENT	Black	24	96,0	22	91,7	22,727	22,610	31	100,0	28	90,3	27,778	19,714
FU MONTH 18	Black	23	92,0	17	73,9	28,105	21,559	29	93,5	24	82,8	42,824	29,737
FU MONTH 24	Black	22	88,0	18	81,8	22,840	18,853	28	90,3	23	82,1	25,121	19,597
FU MONTH 36	Black	22	88,0	18	81,8	19,136	21,493	26	83,9	20	76,9	31,111	25,895
BASELINE	Asian	477	100,0	474	99,4	24,109	16,895	484	100,0	480	99,2	23,542	17,471
END OF ANTHRACYCLINE	Asian	370	77,6	361	97,6	19,021	16,872	375	77,5	368	98,1	20,531	17,122
WEEK 13	Asian	455	95,4	449	98,7	21,282	18,684	466	96,3	465	99,8	24,277	19,135
WEEK 25	Asian	450	94,3	449	99,8	21,307	18,335	465	96,1	459	98,7	21,520	18,158
END OF TREATMENT	Asian	475	99,6	452	95,2	20,010	19,647	484	100,0	463	95,7	19,162	17,901
FU MONTH 18	Asian	447	93,7	434	97,1	18,011	17,466	461	95,2	444	96,3	16,992	15,930
FU MONTH 24	Asian	442	92,7	423	95,7	16,260	17,603	445	91,9	421	94,6	16,495	16,544
FU MONTH 36	Asian	424	88,9	402	94,8	15,810	17,406	425	87,8	398	93,6	15,159	16,241
BASELINE	Other	52	100,0	51	98,1	22,004	16,554	51	100,0	50	98,0	26,222	18,065
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	15,936	17,905	36	70,6	36	100,0	18,519	16,587
WEEK 13	Other	49	94,2	49	100,0	14,286	16,820	45	88,2	45	100,0	18,765	21,165
WEEK 25	Other	49	94,2	49	100,0	21,542	19,955	42	82,4	41	97,6	17,886	16,644
END OF TREATMENT	Other	52	100,0	47	90,4	18,203	16,614	50	98,0	47	94,0	16,430	17,907
FU MONTH 18	Other	50	96,2	48	96,0	13,657	14,540	44	86,3	39	88,6	12,536	15,955
FU MONTH 24	Other	49	94,2	45	91,8	15,556	21,763	43	84,3	39	90,7	11,966	12,060
FU MONTH 36	Other	49	94,2	43	87,8	11,886	18,998	39	76,5	33	84,6	11,111	11,453
BASELINE	Missing	5	100,0	5	100,0	24,444	4,969	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	20,000	29,814	2	100,0	2	100,0	0,000	0,000
WEEK 13	Missing	5	100,0	5	100,0	15,556	18,592	2	100,0	2	100,0	0,000	0,000

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	13,333	9,296	2	100,0	2	100,0	5,556	7,857
END OF TREATMENT	Missing	5	100,0	4	80,0	22,222	25,660	2	100,0	1	50,0	0,000	NE
FU MONTH 18	Missing	5	100,0	4	80,0	8,333	10,638	2	100,0	2	100,0	11,111	15,713
FU MONTH 24	Missing	5	100,0	4	80,0	22,222	20,286	2	100,0	2	100,0	0,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	15,556	16,851	2	100,0	2	100,0	0,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC12_SG.xls
11AUG2020 16:26

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	280	15,5	25,476	32,329	1823	100,0	255	14,0	22,092	28,293
END OF ANTHRACYCLINE	n/a	1432	79,1	1093	76,3	43,580	36,127	1446	79,3	1121	77,5	44,484	37,021
WEEK 13	n/a	1688	93,2	887	52,5	42,014	36,233	1725	94,6	932	54,0	43,741	36,301
WEEK 25	n/a	1645	90,8	349	21,2	37,536	35,757	1688	92,6	369	21,9	40,470	36,452
END OF TREATMENT	n/a	1794	99,1	209	11,6	25,678	30,573	1811	99,3	232	12,8	26,006	33,390
FU MONTH 18	n/a	1663	91,8	240	14,4	22,500	27,834	1688	92,6	315	18,7	25,714	29,953
FU MONTH 24	n/a	1633	90,2	231	14,1	22,944	28,281	1638	89,9	260	15,9	24,487	29,048
FU MONTH 36	n/a	1571	86,7	310	19,7	26,559	30,822	1556	85,4	352	22,6	25,758	30,079
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	4	7,8	16,667	33,333	43	100,0	5	11,6	33,333	40,825
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	29	80,6	43,678	38,938	26	60,5	20	76,9	35,000	42,543
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	25	54,3	48,000	36,107	40	93,0	21	52,5	39,683	35,931
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	13	29,5	30,769	31,802	38	88,4	10	26,3	33,333	38,490
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	6	11,8	16,667	40,825	42	97,7	4	9,5	25,000	50,000
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	6	13,0	38,889	49,065	39	90,7	3	7,7	55,556	38,490

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	9	19,6	29,630	42,310	39	90,7	4	10,3	33,333	47,140
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	12	26,1	41,667	37,939	39	90,7	8	20,5	29,167	37,533
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	34	13,2	19,608	29,721	278	100,0	34	12,2	25,490	30,769
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	141	75,4	45,390	37,433	203	73,0	159	78,3	46,122	38,209
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	134	54,0	41,791	38,058	263	94,6	152	57,8	47,149	36,078
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	49	20,2	42,177	36,499	256	92,1	53	20,7	38,365	34,836
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	24	9,4	19,444	29,352	276	99,3	41	14,9	27,642	32,406
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	29	11,8	22,989	33,456	259	93,2	57	22,0	23,392	28,147
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	38	15,6	25,439	28,405	256	92,1	50	19,5	25,333	27,405
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	45	19,0	30,370	38,809	251	90,3	53	21,1	23,899	28,024
BASELINE	1-3 positive nodes	907	100,0	140	15,4	24,524	32,139	900	100,0	127	14,1	23,360	29,492
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	537	75,3	43,513	35,732	707	78,6	543	76,8	44,567	37,263
WEEK 13	1-3 positive nodes	847	93,4	449	53,0	43,653	36,798	854	94,9	463	54,2	42,189	36,446
WEEK 25	1-3 positive nodes	825	91,0	163	19,8	38,855	37,454	836	92,9	176	21,1	40,530	37,695
END OF TREATMENT	1-3 positive nodes	899	99,1	101	11,2	27,393	31,762	897	99,7	114	12,7	29,532	36,233
FU MONTH 18	1-3 positive nodes	838	92,4	114	13,6	19,298	24,649	852	94,7	166	19,5	28,112	30,255

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	116	14,0	22,701	26,228	830	92,2	137	16,5	24,088	28,791
FU MONTH 36	1-3 positive nodes	804	88,6	156	19,4	26,282	29,575	794	88,2	184	23,2	23,370	29,831
BASELINE	>= 4 positive nodes	596	100,0	102	17,1	29,085	33,390	602	100,0	89	14,8	18,352	24,624
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	386	77,8	43,005	36,098	510	84,7	399	78,2	44,194	35,977
WEEK 13	>= 4 positive nodes	547	91,8	279	51,0	38,949	34,342	568	94,4	296	52,1	44,707	36,232
WEEK 25	>= 4 positive nodes	533	89,4	124	23,3	34,677	33,576	558	92,7	130	23,3	41,795	35,537
END OF TREATMENT	>= 4 positive nodes	590	99,0	78	13,2	26,068	28,754	596	99,0	73	12,2	19,635	27,686
FU MONTH 18	>= 4 positive nodes	533	89,4	91	17,1	25,275	27,818	538	89,4	89	16,5	21,723	29,772
FU MONTH 24	>= 4 positive nodes	516	86,6	68	13,2	21,078	29,872	513	85,2	69	13,5	24,155	30,187
FU MONTH 36	>= 4 positive nodes	484	81,2	97	20,0	23,368	27,287	472	78,4	107	22,7	30,530	30,756
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	217	15,1	26,267	32,887	1448	100,0	211	14,6	23,539	28,893
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1092	76,4	43,529	36,103	1444	99,7	1120	77,6	44,464	37,032
WEEK 13	Anthracycline containing regimen	1347	93,6	625	46,4	42,987	36,510	1374	94,9	645	46,9	42,016	36,971
WEEK 25	Anthracycline containing regimen	1311	91,1	223	17,0	35,725	35,715	1346	93,0	228	16,9	36,404	35,747
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	157	11,0	27,601	31,392	1444	99,7	172	11,9	25,969	33,586

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	173	13,0	21,580	26,105	1340	92,5	243	18,1	27,023	30,851
FU MONTH 24	Anthracycline containing regimen	1306	90,8	166	12,7	20,281	26,406	1308	90,3	193	14,8	25,389	29,368
FU MONTH 36	Anthracycline containing regimen	1259	87,5	229	18,2	25,036	28,852	1244	85,9	257	20,7	26,200	29,991
BASELINE	Non-anthracycline containing regimen	372	100,0	63	16,9	22,751	30,424	375	100,0	44	11,7	15,152	24,330
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	1	33,3	100,000	NE	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	262	76,8	39,695	35,525	351	93,6	287	81,8	47,619	34,495
WEEK 25	Non-anthracycline containing regimen	334	89,8	126	37,7	40,741	35,749	342	91,2	141	41,2	47,045	36,747
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	52	14,2	19,872	27,424	367	97,9	60	16,3	26,111	33,102
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	67	20,1	24,876	31,963	348	92,8	72	20,7	21,296	26,422
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	65	19,9	29,744	31,800	330	88,0	67	20,3	21,891	28,160
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	81	26,0	30,864	35,660	312	83,2	95	30,4	24,561	30,446
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	130	15,0	24,103	32,420	858	100,0	107	12,5	21,184	26,852
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	512	76,2	43,555	35,965	661	77,0	520	78,7	45,449	37,995
WEEK 13	Negative (ER and PgR negative)	815	94,3	457	56,1	41,284	36,575	804	93,7	466	58,0	44,134	36,122
WEEK 25	Negative (ER and PgR negative)	799	92,5	171	21,4	38,402	35,796	786	91,6	186	23,7	39,785	36,763
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	103	12,0	22,330	30,745	854	99,5	117	13,7	24,217	31,142
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	111	13,9	24,324	29,796	781	91,0	147	18,8	26,757	29,361
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	118	15,0	22,599	27,522	763	88,9	123	16,1	24,932	26,855
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	149	19,8	29,530	34,338	735	85,7	156	21,2	24,786	28,555
BASELINE	Positive (ER and/or PgR positive)	947	100,0	150	15,8	26,667	32,311	965	100,0	148	15,3	22,748	29,364
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	581	76,4	43,603	36,300	785	81,3	601	76,6	43,649	36,169
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	430	49,3	42,791	35,892	921	95,4	466	50,6	43,348	36,513
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	178	21,0	36,704	35,801	902	93,5	183	20,3	41,166	36,221
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	106	11,3	28,931	30,194	957	99,2	115	12,0	27,826	35,577
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	129	15,0	20,930	26,044	907	94,0	168	18,5	24,802	30,519
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	113	13,4	23,304	29,170	875	90,7	137	15,7	24,088	30,978

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	161	19,7	23,810	26,985	821	85,1	196	23,9	26,531	31,291
Geographical region II													
BASELINE	USA/Canada	265	100,0	41	15,5	17,886	28,961	260	100,0	29	11,2	12,644	25,841
END OF ANTHRACYCLINE	USA/Canada	109	41,1	82	75,2	39,837	32,474	111	42,7	81	73,0	45,267	33,044
WEEK 13	USA/Canada	242	91,3	162	66,9	37,654	35,273	236	90,8	165	69,9	47,879	34,588
WEEK 25	USA/Canada	234	88,3	67	28,6	37,811	36,189	230	88,5	70	30,4	39,524	35,118
END OF TREATMENT	USA/Canada	259	97,7	46	17,8	18,841	22,935	255	98,1	47	18,4	18,440	30,934
FU MONTH 18	USA/Canada	238	89,8	39	16,4	17,094	28,482	231	88,8	32	13,9	27,083	32,171
FU MONTH 24	USA/Canada	231	87,2	40	17,3	25,833	31,566	224	86,2	31	13,8	13,978	23,997
FU MONTH 36	USA/Canada	223	84,2	41	18,4	21,951	33,838	205	78,8	40	19,5	17,500	29,223
BASELINE	Western Europe	827	100,0	97	11,7	25,086	35,037	822	100,0	96	11,7	24,653	32,532
END OF ANTHRACYCLINE	Western Europe	732	88,5	538	73,5	49,628	37,851	728	88,6	542	74,5	47,786	38,109
WEEK 13	Western Europe	764	92,4	311	40,7	48,553	39,129	778	94,6	331	42,5	48,943	38,508
WEEK 25	Western Europe	738	89,2	117	15,9	39,601	40,098	750	91,2	120	16,0	45,833	39,856
END OF TREATMENT	Western Europe	821	99,3	88	10,7	33,333	36,445	817	99,4	83	10,2	34,940	39,613
FU MONTH 18	Western Europe	754	91,2	83	11,0	22,490	29,498	764	92,9	123	16,1	26,016	33,751
FU MONTH 24	Western Europe	739	89,4	83	11,2	20,884	29,774	747	90,9	109	14,6	29,052	34,277
FU MONTH 36	Western Europe	713	86,2	126	17,7	29,101	33,727	712	86,6	129	18,1	29,716	34,921
BASELINE	Asia Pacific	490	100,0	99	20,2	30,976	30,953	512	100,0	85	16,6	26,275	25,766
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	309	81,1	35,707	32,921	397	77,5	337	84,9	36,696	35,288
WEEK 13	Asia Pacific	466	95,1	305	65,5	40,109	34,167	493	96,3	325	65,9	36,513	33,541
WEEK 25	Asia Pacific	461	94,1	116	25,2	37,644	32,162	492	96,1	126	25,6	37,566	32,382

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	62	12,7	20,968	26,471	512	100,0	74	14,5	20,270	24,562
FU MONTH 18	Asia Pacific	459	93,7	86	18,7	26,744	25,473	485	94,7	121	24,9	25,069	25,920
FU MONTH 24	Asia Pacific	454	92,7	70	15,4	25,238	25,019	470	91,8	92	19,6	22,826	24,673
FU MONTH 36	Asia Pacific	437	89,2	102	23,3	27,778	25,727	453	88,5	140	30,9	24,524	25,480
BASELINE	Latin America	43	100,0	9	20,9	18,519	37,680	47	100,0	10	21,3	16,667	32,394
END OF ANTHRACYCLINE	Latin America	29	67,4	26	89,7	32,051	31,945	32	68,1	29	90,6	47,126	40,353
WEEK 13	Latin America	40	93,0	33	82,5	31,313	36,266	44	93,6	34	77,3	50,000	36,927
WEEK 25	Latin America	39	90,7	15	38,5	24,444	32,038	44	93,6	18	40,9	25,926	29,273
END OF TREATMENT	Latin America	42	97,7	4	9,5	16,667	19,245	45	95,7	10	22,2	23,333	31,623
FU MONTH 18	Latin America	41	95,3	10	24,4	16,667	32,394	42	89,4	12	28,6	27,778	31,248
FU MONTH 24	Latin America	40	93,0	12	30,0	22,222	29,588	41	87,2	11	26,8	24,242	26,208
FU MONTH 36	Latin America	38	88,4	8	21,1	16,667	35,635	37	78,7	15	40,5	17,778	24,774
BASELINE	Other	186	100,0	34	18,3	21,569	29,453	182	100,0	35	19,2	14,286	18,587
END OF ANTHRACYCLINE	Other	181	97,3	138	76,2	42,029	34,950	178	97,8	132	74,2	49,747	35,787
WEEK 13	Other	176	94,6	76	43,2	36,842	30,101	174	95,6	77	44,3	40,260	36,410
WEEK 25	Other	173	93,0	34	19,7	35,294	32,764	172	94,5	35	20,3	41,905	42,274
END OF TREATMENT	Other	185	99,5	9	4,9	22,222	16,667	182	100,0	18	9,9	29,630	34,087
FU MONTH 18	Other	171	91,9	22	12,9	18,182	26,681	166	91,2	27	16,3	24,691	27,100
FU MONTH 24	Other	169	90,9	26	15,4	19,231	26,954	156	85,7	17	10,9	23,529	19,596
FU MONTH 36	Other	160	86,0	33	20,6	21,212	28,648	149	81,9	28	18,8	29,762	29,171
Protocol version													
BASELINE	Protocol A	1240	100,0	201	16,2	26,700	33,833	1246	100,0	178	14,3	21,723	27,945

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	747	75,9	43,730	36,741	988	79,3	765	77,4	43,834	37,034
WEEK 13	Protocol A	1155	93,1	605	52,4	42,534	36,517	1180	94,7	635	53,8	43,780	37,177
WEEK 25	Protocol A	1125	90,7	239	21,2	38,633	36,792	1157	92,9	245	21,2	40,408	36,774
END OF TREATMENT	Protocol A	1229	99,1	140	11,4	25,238	30,417	1236	99,2	150	12,1	27,556	35,130
FU MONTH 18	Protocol A	1142	92,1	171	15,0	22,222	28,697	1156	92,8	214	18,5	25,857	31,419
FU MONTH 24	Protocol A	1124	90,6	167	14,9	23,154	28,743	1127	90,4	176	15,6	24,053	28,879
FU MONTH 36	Protocol A	1087	87,7	224	20,6	26,786	32,605	1069	85,8	235	22,0	25,674	30,631
BASELINE	Protocol Amendment B	571	100,0	79	13,8	22,363	28,103	577	100,0	77	13,3	22,944	29,250
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	346	77,2	43,256	34,814	458	79,4	356	77,7	45,880	37,007
WEEK 13	Protocol Amendment B	533	93,3	282	52,9	40,898	35,653	545	94,5	297	54,5	43,659	34,414
WEEK 25	Protocol Amendment B	520	91,1	110	21,2	35,152	33,436	531	92,0	124	23,4	40,591	35,957
END OF TREATMENT	Protocol Amendment B	565	98,9	69	12,2	26,570	31,091	575	99,7	82	14,3	23,171	29,947
FU MONTH 18	Protocol Amendment B	521	91,2	69	13,2	23,188	25,759	532	92,2	101	19,0	25,413	26,728
FU MONTH 24	Protocol Amendment B	509	89,1	64	12,6	22,396	27,252	511	88,6	84	16,4	25,397	29,552
FU MONTH 36	Protocol Amendment B	484	84,8	86	17,8	25,969	25,770	487	84,4	117	24,0	25,926	29,070
Nodal status													
BASELINE	0 positive nodes	308	100,0	38	12,3	19,298	29,644	321	100,0	39	12,1	26,496	31,696
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	170	76,2	45,098	37,582	229	71,3	179	78,2	44,879	38,748
WEEK 13	0 positive nodes	294	95,5	159	54,1	42,767	37,715	303	94,4	173	57,1	46,243	36,039
WEEK 25	0 positive nodes	287	93,2	62	21,6	39,785	35,625	294	91,6	63	21,4	37,566	35,161
END OF TREATMENT	0 positive nodes	305	99,0	30	9,8	18,889	31,175	318	99,1	45	14,2	27,407	33,551
FU MONTH 18	0 positive nodes	292	94,8	35	12,0	25,714	36,232	298	92,8	60	20,1	25,000	29,192

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	47	16,2	26,241	31,034	295	91,9	54	18,3	25,926	28,716
FU MONTH 36	0 positive nodes	283	91,9	57	20,1	32,749	38,571	290	90,3	61	21,0	24,590	29,124
BASELINE	>= 1 positive nodes	1503	100,0	242	16,1	26,446	32,682	1502	100,0	216	14,4	21,296	27,640
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	923	76,3	43,301	35,867	1217	81,0	942	77,4	44,409	36,705
WEEK 13	>= 1 positive nodes	1394	92,7	728	52,2	41,850	35,926	1422	94,7	759	53,4	43,171	36,360
WEEK 25	>= 1 positive nodes	1358	90,4	287	21,1	37,050	35,829	1394	92,8	306	22,0	41,068	36,740
END OF TREATMENT	>= 1 positive nodes	1489	99,1	179	12,0	26,816	30,411	1493	99,4	187	12,5	25,668	33,433
FU MONTH 18	>= 1 positive nodes	1371	91,2	205	15,0	21,951	26,207	1390	92,5	255	18,3	25,882	30,183
FU MONTH 24	>= 1 positive nodes	1343	89,4	184	13,7	22,101	27,561	1343	89,4	206	15,3	24,110	29,192
FU MONTH 36	>= 1 positive nodes	1288	85,7	253	19,6	25,165	28,699	1266	84,3	291	23,0	26,002	30,319
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	123	14,1	23,577	30,992	885	100,0	132	14,9	23,737	27,484
END OF ANTHRACYCLINE	Premenopausal	708	81,1	546	77,1	41,636	34,686	726	82,0	568	78,2	43,251	36,254
WEEK 13	Premenopausal	841	96,3	410	48,8	41,463	35,181	852	96,3	426	50,0	41,158	34,849
WEEK 25	Premenopausal	825	94,5	150	18,2	36,889	34,789	838	94,7	158	18,9	38,397	33,897
END OF TREATMENT	Premenopausal	866	99,2	96	11,1	22,917	28,331	881	99,5	98	11,1	22,109	31,729
FU MONTH 18	Premenopausal	819	93,8	100	12,2	23,000	30,593	835	94,4	151	18,1	22,075	28,255
FU MONTH 24	Premenopausal	803	92,0	96	12,0	21,875	28,950	807	91,2	111	13,8	20,120	26,697

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	140	18,3	20,000	28,216	773	87,3	160	20,7	24,792	29,965
BASELINE	Postmenopausal	933	100,0	156	16,7	27,137	33,399	929	100,0	123	13,2	20,325	29,145
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	543	75,5	45,734	37,415	711	76,5	546	76,8	45,910	37,785
WEEK 13	Postmenopausal	842	90,2	476	56,5	42,507	37,180	864	93,0	502	58,1	46,215	37,350
WEEK 25	Postmenopausal	815	87,4	199	24,4	38,023	36,550	841	90,5	210	25,0	42,222	38,241
END OF TREATMENT	Postmenopausal	923	98,9	112	12,1	28,274	32,330	921	99,1	134	14,5	28,856	34,392
FU MONTH 18	Postmenopausal	839	89,9	140	16,7	22,143	25,792	844	90,9	163	19,3	29,243	31,158
FU MONTH 24	Postmenopausal	825	88,4	133	16,1	24,060	27,935	823	88,6	148	18,0	27,928	30,380
FU MONTH 36	Postmenopausal	801	85,9	167	20,8	32,535	31,887	776	83,5	190	24,5	26,491	30,380
BASELINE	Unknown/Missing	5	100,0	1	20,0	0,000	NE	9	100,0	0	0,0	NE	NE
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	4	80,0	16,667	33,333	9	100,0	7	77,8	33,333	38,490
WEEK 13	Unknown/Missing	5	100,0	1	20,0	33,333	NE	9	100,0	4	44,4	8,333	16,667
WEEK 25	Unknown/Missing	5	100,0	0	0,0	NE	NE	9	100,0	1	11,1	0,000	NE
END OF TREATMENT	Unknown/Missing	5	100,0	1	20,0	0,000	NE	9	100,0	0	0,0	NE	NE
FU MONTH 18	Unknown/Missing	5	100,0	0	0,0	NE	NE	9	100,0	1	11,1	0,000	NE
FU MONTH 24	Unknown/Missing	5	100,0	2	40,0	0,000	0,000	8	88,9	1	12,5	0,000	NE
FU MONTH 36	Unknown/Missing	5	100,0	3	60,0	0,000	0,000	7	77,8	2	28,6	33,333	0,000
Age II													
BASELINE	< 65	1581	100,0	248	15,7	25,806	32,400	1604	100,0	223	13,9	21,674	27,647
END OF ANTHRACYCLINE	< 65	1268	80,2	977	77,1	42,921	35,743	1287	80,2	1004	78,0	44,024	36,804
WEEK 13	< 65	1497	94,7	770	51,4	41,818	36,103	1529	95,3	808	52,8	42,781	35,824

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	289	19,7	36,448	35,707	1501	93,6	308	20,5	38,745	35,687
END OF TREATMENT	< 65	1569	99,2	174	11,1	23,563	28,901	1596	99,5	193	12,1	24,352	32,631
FU MONTH 18	< 65	1474	93,2	205	13,9	21,626	27,288	1497	93,3	271	18,1	24,600	29,003
FU MONTH 24	< 65	1446	91,5	194	13,4	21,821	27,760	1450	90,4	225	15,5	24,296	29,586
FU MONTH 36	< 65	1390	87,9	273	19,6	25,275	29,981	1383	86,2	303	21,9	25,853	29,761
BASELINE	>= 65	230	100,0	32	13,9	22,917	32,171	219	100,0	32	14,6	25,000	32,791
END OF ANTHRACYCLINE	>= 65	164	71,3	116	70,7	49,138	38,938	159	72,6	117	73,6	48,433	38,778
WEEK 13	>= 65	191	83,0	117	61,3	43,305	37,207	196	89,5	124	63,3	50,000	38,840
WEEK 25	>= 65	181	78,7	60	33,1	42,778	35,834	187	85,4	61	32,6	49,180	39,255
END OF TREATMENT	>= 65	225	97,8	35	15,6	36,190	36,489	215	98,2	39	18,1	34,188	36,263
FU MONTH 18	>= 65	189	82,2	35	18,5	27,619	30,770	191	87,2	44	23,0	32,576	34,841
FU MONTH 24	>= 65	187	81,3	37	19,8	28,829	30,593	188	85,8	35	18,6	25,714	25,675
FU MONTH 36	>= 65	181	78,7	37	20,4	36,036	35,467	173	79,0	49	28,3	25,170	32,297
Histological grade													
BASELINE	Grade 1	32	100,0	5	15,6	20,000	44,721	24	100,0	6	25,0	11,111	17,213
END OF ANTHRACYCLINE	Grade 1	18	56,3	12	66,7	47,222	38,817	17	70,8	15	88,2	24,444	32,038
WEEK 13	Grade 1	31	96,9	18	58,1	48,148	32,784	23	95,8	20	87,0	26,667	27,784
WEEK 25	Grade 1	31	96,9	7	22,6	42,857	41,786	23	95,8	6	26,1	50,000	34,960
END OF TREATMENT	Grade 1	31	96,9	2	6,5	33,333	47,140	24	100,0	3	12,5	22,222	19,245
FU MONTH 18	Grade 1	30	93,8	4	13,3	8,333	16,667	23	95,8	8	34,8	20,833	35,355
FU MONTH 24	Grade 1	28	87,5	3	10,7	44,444	50,918	23	95,8	2	8,7	16,667	23,570
FU MONTH 36	Grade 1	27	84,4	4	14,8	41,667	50,000	22	91,7	6	27,3	16,667	18,257
BASELINE	Grade 2	552	100,0	99	17,9	28,956	34,222	557	100,0	90	16,2	20,370	25,817
END OF ANTHRACYCLINE	Grade 2	445	80,6	345	77,5	41,063	34,824	446	80,1	351	78,7	46,059	36,811

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	275	54,2	43,152	35,406	524	94,1	293	55,9	41,866	35,210
WEEK 25	Grade 2	494	89,5	128	25,9	36,979	34,043	515	92,5	125	24,3	40,800	35,130
END OF TREATMENT	Grade 2	548	99,3	74	13,5	29,279	32,149	553	99,3	84	15,2	23,413	32,635
FU MONTH 18	Grade 2	507	91,8	81	16,0	23,868	29,456	517	92,8	99	19,1	28,956	30,731
FU MONTH 24	Grade 2	501	90,8	82	16,4	21,138	27,968	500	89,8	78	15,6	23,504	32,282
FU MONTH 36	Grade 2	487	88,2	104	21,4	25,962	29,726	476	85,5	118	24,8	31,921	34,148
BASELINE	Grade 3	1161	100,0	169	14,6	23,274	30,819	1173	100,0	153	13,0	23,965	30,218
END OF ANTHRACYCLINE	Grade 3	918	79,1	698	76,0	44,747	36,532	919	78,3	698	76,0	44,317	36,988
WEEK 13	Grade 3	1088	93,7	555	51,0	41,982	36,839	1114	95,0	580	52,1	45,575	36,828
WEEK 25	Grade 3	1059	91,2	206	19,5	37,702	36,623	1087	92,7	231	21,3	40,115	37,393
END OF TREATMENT	Grade 3	1150	99,1	127	11,0	23,360	29,191	1165	99,3	137	11,8	27,494	34,275
FU MONTH 18	Grade 3	1067	91,9	149	14,0	21,700	26,826	1085	92,5	198	18,2	23,232	28,282
FU MONTH 24	Grade 3	1046	90,1	138	13,2	22,947	27,845	1053	89,8	172	16,3	24,612	28,066
FU MONTH 36	Grade 3	1002	86,3	192	19,2	25,868	30,828	999	85,2	217	21,7	22,581	27,538
BASELINE	Unevaluable/Unknown/Missing	66	100,0	7	10,6	33,333	33,333	69	100,0	6	8,7	11,111	17,213
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	38	74,5	43,860	39,597	64	92,8	57	89,1	42,105	39,100
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	39	62,9	31,624	34,155	64	92,8	39	60,9	39,316	38,138
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	8	13,1	37,500	41,547	63	91,3	7	11,1	38,095	35,635
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	6	9,2	27,778	38,968	69	100,0	8	11,6	29,167	33,034
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	6	10,2	33,333	36,515	63	91,3	10	15,9	46,667	42,164

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	8	13,8	33,333	30,861	62	89,9	8	12,9	33,333	17,817
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	10	18,2	40,000	34,427	59	85,5	11	18,6	27,273	29,129
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	102	14,0	24,183	34,836	715	100,0	91	12,7	24,176	30,252
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	447	75,5	46,160	38,006	572	80,0	425	74,3	44,941	37,354
WEEK 13	Breast conserving surgery	677	93,0	338	49,9	45,759	38,305	673	94,1	348	51,7	45,211	36,489
WEEK 25	Breast conserving surgery	665	91,3	126	18,9	37,831	36,357	654	91,5	135	20,6	40,741	38,989
END OF TREATMENT	Breast conserving surgery	722	99,2	75	10,4	28,889	33,483	711	99,4	91	12,8	29,670	34,588
FU MONTH 18	Breast conserving surgery	678	93,1	87	12,8	21,073	27,896	659	92,2	118	17,9	28,814	31,702
FU MONTH 24	Breast conserving surgery	666	91,5	92	13,8	23,913	30,593	644	90,1	104	16,1	28,526	31,303
FU MONTH 36	Breast conserving surgery	651	89,4	119	18,3	26,331	33,579	616	86,2	141	22,9	30,260	34,710
BASELINE	Mastectomy	1083	100,0	178	16,4	26,217	30,878	1107	100,0	164	14,8	20,935	27,172
END OF ANTHRACYCLINE	Mastectomy	840	77,6	646	76,9	41,796	34,685	873	78,9	695	79,6	44,221	36,865
WEEK 13	Mastectomy	1011	93,4	549	54,3	39,709	34,731	1051	94,9	584	55,6	42,865	36,191
WEEK 25	Mastectomy	980	90,5	223	22,8	37,369	35,495	1033	93,3	234	22,7	40,313	34,990
END OF TREATMENT	Mastectomy	1072	99,0	134	12,5	23,881	28,791	1099	99,3	141	12,8	23,641	32,499
FU MONTH 18	Mastectomy	985	91,0	153	15,5	23,312	27,858	1028	92,9	196	19,1	23,469	28,328
FU MONTH 24	Mastectomy	967	89,3	139	14,4	22,302	26,736	993	89,7	155	15,6	21,720	27,285

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	191	20,8	26,702	29,063	939	84,8	211	22,5	22,749	26,199
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	95	14,4	27,018	35,161	665	100,0	81	12,2	23,045	28,695
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	391	75,3	45,610	36,630	523	78,6	401	76,7	45,137	37,257
WEEK 13	0 - < 2 cm	620	93,9	302	48,7	42,274	37,417	631	94,9	336	53,2	42,063	35,825
WEEK 25	0 - < 2 cm	608	92,1	125	20,6	39,733	35,845	617	92,8	143	23,2	40,093	37,853
END OF TREATMENT	0 - < 2 cm	655	99,2	66	10,1	25,758	31,916	661	99,4	83	12,6	21,687	31,422
FU MONTH 18	0 - < 2 cm	617	93,5	74	12,0	22,973	26,418	624	93,8	117	18,8	25,071	28,670
FU MONTH 24	0 - < 2 cm	607	92,0	91	15,0	21,612	26,931	606	91,1	90	14,9	21,481	25,631
FU MONTH 36	0 - < 2 cm	596	90,3	114	19,1	25,731	31,989	580	87,2	128	22,1	27,083	30,668
BASELINE	>= 2 - < 5 cm	1009	100,0	163	16,2	24,744	31,337	991	100,0	151	15,2	20,971	28,183
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	617	77,4	42,410	35,742	789	79,6	617	78,2	44,895	37,117
WEEK 13	>= 2 - < 5 cm	935	92,7	519	55,5	41,875	35,239	940	94,9	513	54,6	44,704	36,184
WEEK 25	>= 2 - < 5 cm	910	90,2	197	21,6	37,225	36,134	919	92,7	187	20,3	40,107	35,273
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	119	11,9	26,050	29,801	985	99,4	120	12,2	25,556	33,118

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	144	15,6	21,759	28,240	914	92,2	171	18,7	27,290	31,246
FU MONTH 24	>= 2 - < 5 cm	905	89,7	125	13,8	24,533	29,977	889	89,7	150	16,9	27,111	30,747
FU MONTH 36	>= 2 - < 5 cm	857	84,9	173	20,2	27,553	30,584	839	84,7	197	23,5	25,042	30,193
BASELINE	>= 5 cm	139	100,0	22	15,8	24,242	27,568	165	100,0	22	13,3	25,758	28,971
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	83	73,5	41,767	36,382	132	80,0	102	77,3	39,542	35,640
WEEK 13	>= 5 cm	130	93,5	64	49,2	40,625	38,704	152	92,1	82	53,9	44,715	39,273
WEEK 25	>= 5 cm	124	89,2	27	21,8	29,630	32,467	150	90,9	38	25,3	44,737	37,390
END OF TREATMENT	>= 5 cm	138	99,3	24	17,4	23,611	31,819	163	98,8	29	17,8	40,230	37,139
FU MONTH 18	>= 5 cm	120	86,3	22	18,3	25,758	30,744	148	89,7	25	16,9	17,333	25,676
FU MONTH 24	>= 5 cm	118	84,9	15	12,7	17,778	21,331	141	85,5	18	12,8	18,519	30,726
FU MONTH 36	>= 5 cm	115	82,7	22	19,1	24,242	27,568	135	81,8	26	19,3	24,359	27,580
BASELINE	Missing	3	100,0	0	0,0	NE	NE	2	100,0	1	50,0	33,333	NE
END OF ANTHRACYCLINE	Missing	3	100,0	2	66,7	83,333	23,570	2	100,0	1	50,0	33,333	NE
WEEK 13	Missing	3	100,0	2	66,7	83,333	23,570	2	100,0	1	50,0	33,333	NE
WEEK 25	Missing	3	100,0	0	0,0	NE	NE	2	100,0	1	50,0	0,000	NE
END OF TREATMENT	Missing	3	100,0	0	0,0	NE	NE	2	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	3	100,0	0	0,0	NE	NE	2	100,0	2	100,0	33,333	47,140
FU MONTH 24	Missing	3	100,0	0	0,0	NE	NE	2	100,0	2	100,0	16,667	23,570
FU MONTH 36	Missing	3	100,0	1	33,3	0,000	NE	2	100,0	1	50,0	33,333	NE
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	208	15,4	25,321	32,268	1350	100,0	182	13,5	22,894	29,436
END OF ANTHRACYCLINE	Yes	1103	81,9	850	77,1	43,490	36,069	1104	81,8	863	78,2	44,457	37,240
WEEK 13	Yes	1308	97,1	657	50,2	42,567	36,755	1324	98,1	692	52,3	44,605	36,508
WEEK 25	Yes	1277	94,8	261	20,4	37,292	36,122	1302	96,4	270	20,7	39,012	36,817

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	158	11,7	25,738	30,541	1350	100,0	168	12,4	26,389	33,800
FU MONTH 18	Yes	1291	95,8	185	14,3	22,883	28,213	1298	96,1	237	18,3	25,457	30,282
FU MONTH 24	Yes	1266	94,0	180	14,2	22,407	28,588	1260	93,3	190	15,1	25,614	30,265
FU MONTH 36	Yes	1219	90,5	236	19,4	25,000	30,770	1195	88,5	258	21,6	28,036	31,975
BASELINE	No	464	100,0	72	15,5	25,926	32,728	473	100,0	73	15,4	20,091	25,300
END OF ANTHRACYCLINE	No	329	70,9	243	73,9	43,896	36,402	342	72,3	258	75,4	44,574	36,352
WEEK 13	No	380	81,9	230	60,5	40,435	34,728	401	84,8	240	59,9	41,250	35,656
WEEK 25	No	368	79,3	88	23,9	38,258	34,847	386	81,6	99	25,6	44,444	35,315
END OF TREATMENT	No	447	96,3	51	11,4	25,490	30,975	461	97,5	64	13,9	25,000	32,530
FU MONTH 18	No	372	80,2	55	14,8	21,212	26,731	390	82,5	78	20,0	26,496	29,108
FU MONTH 24	No	367	79,1	51	13,9	24,837	27,360	378	79,9	70	18,5	21,429	25,402
FU MONTH 36	No	352	75,9	74	21,0	31,532	30,666	361	76,3	94	26,0	19,504	23,140
Race													
BASELINE	White	1252	100,0	162	12,9	21,193	31,471	1255	100,0	152	12,1	20,395	29,479
END OF ANTHRACYCLINE	White	1010	80,7	753	74,6	46,392	36,777	1018	81,1	759	74,6	46,860	37,021
WEEK 13	White	1158	92,5	527	45,5	43,137	36,981	1183	94,3	559	47,3	46,333	36,878
WEEK 25	White	1120	89,5	200	17,9	38,000	37,367	1150	91,6	211	18,3	42,180	38,705
END OF TREATMENT	White	1238	98,9	126	10,2	29,894	32,613	1244	99,1	134	10,8	28,607	36,367
FU MONTH 18	White	1138	90,9	137	12,0	20,925	29,430	1152	91,8	174	15,1	25,479	31,789
FU MONTH 24	White	1115	89,1	137	12,3	21,655	29,592	1120	89,2	151	13,5	25,607	31,374
FU MONTH 36	White	1071	85,5	197	18,4	25,888	32,834	1064	84,8	200	18,8	26,000	32,254
BASELINE	Black	25	100,0	6	24,0	5,556	13,608	31	100,0	7	22,6	4,762	12,599
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	37,037	35,136	15	48,4	11	73,3	54,545	47,779
WEEK 13	Black	21	84,0	14	66,7	35,714	35,720	29	93,5	21	72,4	50,794	41,659

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	11	52,4	27,273	38,925	29	93,5	18	62,1	42,593	42,481
END OF TREATMENT	Black	24	96,0	10	41,7	16,667	23,570	31	100,0	10	32,3	20,000	35,832
FU MONTH 18	Black	23	92,0	7	30,4	4,762	12,599	29	93,5	8	27,6	29,167	37,533
FU MONTH 24	Black	22	88,0	7	31,8	4,762	12,599	28	90,3	5	17,9	13,333	18,257
FU MONTH 36	Black	22	88,0	3	13,6	11,111	19,245	26	83,9	8	30,8	37,500	45,207
BASELINE	Asian	477	100,0	99	20,8	33,333	31,944	484	100,0	86	17,8	27,132	25,826
END OF ANTHRACYCLINE	Asian	370	77,6	295	79,7	37,853	33,704	375	77,5	322	85,9	38,095	35,565
WEEK 13	Asian	455	95,4	303	66,6	41,364	34,388	466	96,3	318	68,2	38,260	33,910
WEEK 25	Asian	450	94,3	119	26,4	38,375	32,370	465	96,1	123	26,5	39,024	32,139
END OF TREATMENT	Asian	475	99,6	62	13,1	19,892	25,932	484	100,0	77	15,9	22,511	27,805
FU MONTH 18	Asian	447	93,7	85	19,0	26,667	25,092	461	95,2	123	26,7	25,745	26,929
FU MONTH 24	Asian	442	92,7	73	16,5	27,397	26,260	445	91,9	94	21,1	23,404	25,787
FU MONTH 36	Asian	424	88,9	101	23,8	29,373	26,368	425	87,8	133	31,3	25,313	25,673
BASELINE	Other	52	100,0	12	23,1	22,222	35,770	51	100,0	9	17,6	18,519	33,793
END OF ANTHRACYCLINE	Other	38	73,1	33	86,8	31,313	35,296	36	70,6	28	77,8	50,000	42,066
WEEK 13	Other	49	94,2	40	81,6	32,500	38,109	45	88,2	33	73,3	49,495	40,070
WEEK 25	Other	49	94,2	17	34,7	25,490	32,338	42	82,4	17	40,5	27,451	29,428
END OF TREATMENT	Other	52	100,0	9	17,3	7,407	14,699	50	98,0	11	22,0	24,242	30,151
FU MONTH 18	Other	50	96,2	10	20,0	20,000	32,203	44	86,3	10	22,7	26,667	30,631
FU MONTH 24	Other	49	94,2	13	26,5	23,077	28,495	43	84,3	10	23,3	23,333	27,442
FU MONTH 36	Other	49	94,2	8	16,3	16,667	35,635	39	76,5	11	28,2	18,182	27,340
BASELINE	Missing	5	100,0	1	20,0	100,000	NE	2	100,0	1	50,0	0,000	NE
END OF ANTHRACYCLINE	Missing	5	100,0	3	60,0	55,556	38,490	2	100,0	1	50,0	33,333	NE
WEEK 13	Missing	5	100,0	3	60,0	66,667	57,735	2	100,0	1	50,0	0,000	NE

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	2	40,0	100,000	0,000	2	100,0	0	0,0	NE	NE
END OF TREATMENT	Missing	5	100,0	2	40,0	66,667	47,140	2	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	5	100,0	1	20,0	33,333	NE	2	100,0	0	0,0	NE	NE
FU MONTH 24	Missing	5	100,0	1	20,0	0,000	NE	2	100,0	0	0,0	NE	NE
FU MONTH 36	Missing	5	100,0	1	20,0	0,000	NE	2	100,0	0	0,0	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_SSC13_SG.xls
11AUG2020 16:28

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Body Image Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1744	96,3	78,649	23,950	1823	100,0	1760	96,5	78,035	23,803
END OF ANTHRACYCLINE	n/a	1432	79,1	1337	93,4	67,275	28,081	1446	79,3	1359	94,0	66,180	28,392
WEEK 13	n/a	1688	93,2	1602	94,9	66,641	28,125	1725	94,6	1630	94,5	64,966	28,636
WEEK 25	n/a	1645	90,8	1577	95,9	71,969	26,012	1688	92,6	1594	94,4	71,299	25,972
END OF TREATMENT	n/a	1794	99,1	1567	87,3	76,631	24,595	1811	99,3	1620	89,5	74,383	25,717
FU MONTH 18	n/a	1663	91,8	1475	88,7	79,552	22,966	1688	92,6	1465	86,8	76,409	24,892
FU MONTH 24	n/a	1633	90,2	1421	87,0	80,098	23,723	1638	89,9	1419	86,6	78,610	24,081
FU MONTH 36	n/a	1571	86,7	1382	88,0	81,621	23,405	1556	85,4	1342	86,2	79,910	23,799
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	83,844	21,943	43	100,0	40	93,0	84,583	21,479
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	68,817	27,636	26	60,5	25	96,2	65,667	27,251
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	67,614	28,824	40	93,0	39	97,5	66,880	32,189
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	73,643	27,514	38	88,4	35	92,1	77,937	20,567
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	43	84,3	80,685	19,378	42	97,7	37	88,1	82,357	22,992
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	83,140	22,603	39	90,7	35	89,7	75,238	28,041

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	85,078	22,015	39	90,7	34	87,2	80,882	22,188
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	86,563	19,500	39	90,7	37	94,9	84,910	19,329
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	246	95,7	82,103	23,762	278	100,0	269	96,8	80,194	22,457
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	177	94,7	69,539	27,395	203	73,0	191	94,1	66,259	28,011
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	233	94,0	69,456	27,069	263	94,6	253	96,2	65,349	27,607
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	237	97,5	74,461	24,839	256	92,1	247	96,5	71,851	24,790
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	226	89,0	81,563	23,039	276	99,3	254	92,0	75,448	25,003
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	219	89,0	82,915	22,235	259	93,2	229	88,4	78,481	23,884
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	207	84,8	84,608	20,993	256	92,1	228	89,1	80,811	22,014
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	213	89,9	85,511	22,617	251	90,3	225	89,6	81,074	23,521
BASELINE	1-3 positive nodes	907	100,0	879	96,9	78,912	23,466	900	100,0	867	96,3	78,515	23,496
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	661	92,7	67,293	28,391	707	78,6	666	94,2	66,325	28,800
WEEK 13	1-3 positive nodes	847	93,4	804	94,9	66,290	28,277	854	94,9	801	93,8	65,155	28,481
WEEK 25	1-3 positive nodes	825	91,0	783	94,9	71,878	25,996	836	92,9	784	93,8	71,464	26,281
END OF TREATMENT	1-3 positive nodes	899	99,1	777	86,4	76,019	24,046	897	99,7	808	90,1	74,092	25,822
FU MONTH 18	1-3 positive nodes	838	92,4	732	87,4	79,368	22,369	852	94,7	741	87,0	76,901	24,573

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	722	87,3	79,494	23,952	830	92,2	723	87,1	79,219	23,791
FU MONTH 36	1-3 positive nodes	804	88,6	700	87,1	81,369	23,337	794	88,2	663	83,5	80,644	23,216
BASELINE	>= 4 positive nodes	596	100,0	570	95,6	76,306	24,711	602	100,0	584	97,0	75,880	24,832
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	468	94,4	66,293	27,961	510	84,7	477	93,5	65,974	28,112
WEEK 13	>= 4 positive nodes	547	91,8	521	95,2	65,840	28,295	568	94,4	537	94,5	64,365	29,138
WEEK 25	>= 4 positive nodes	533	89,4	514	96,4	70,817	26,425	558	92,7	528	94,6	70,355	26,356
END OF TREATMENT	>= 4 positive nodes	590	99,0	521	88,3	75,069	26,151	596	99,0	521	87,4	73,747	26,038
FU MONTH 18	>= 4 positive nodes	533	89,4	481	90,2	77,980	24,074	538	89,4	460	85,5	74,674	25,605
FU MONTH 24	>= 4 positive nodes	516	86,6	449	87,0	78,514	24,446	513	85,2	434	84,6	76,261	25,585
FU MONTH 36	>= 4 positive nodes	484	81,2	426	88,0	79,591	24,027	472	78,4	417	88,3	77,671	25,079
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1388	96,5	78,354	24,155	1448	100,0	1399	96,6	78,091	23,945
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1335	93,4	67,245	28,087	1444	99,7	1358	94,0	66,192	28,399
WEEK 13	Anthracycline containing regimen	1347	93,6	1288	95,6	66,718	28,151	1374	94,9	1297	94,4	65,287	28,863
WEEK 25	Anthracycline containing regimen	1311	91,1	1251	95,4	72,968	25,902	1346	93,0	1271	94,4	72,423	25,971
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1253	87,7	76,767	24,441	1444	99,7	1296	89,8	74,668	25,718

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1175	88,4	79,946	22,705	1340	92,5	1173	87,5	76,518	24,950
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1136	87,0	80,529	23,485	1308	90,3	1131	86,5	78,957	24,040
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1102	87,5	81,697	23,239	1244	85,9	1077	86,6	80,179	23,777
BASELINE	Non-anthracycline containing regimen	372	100,0	356	95,7	79,799	23,130	375	100,0	361	96,3	77,816	23,277
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	87,500	17,678	2	0,5	1	50,0	50,000	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	314	92,1	66,322	28,059	351	93,6	333	94,9	63,714	27,745
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	68,132	26,117	342	91,2	323	94,4	66,873	25,540
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	314	86,0	76,088	25,233	367	97,9	324	88,3	73,242	25,723
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	300	89,8	78,009	23,937	348	92,8	292	83,9	75,970	24,698
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	285	87,2	78,382	24,618	330	88,0	288	87,3	77,247	24,237
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	280	89,7	81,319	24,088	312	83,2	265	84,9	78,816	23,900
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	833	96,4	79,045	24,851	858	100,0	831	96,9	78,112	23,783
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	635	94,5	67,454	28,230	661	77,0	620	93,8	65,237	29,883
WEEK 13	Negative (ER and PgR negative)	815	94,3	773	94,8	67,716	27,942	804	93,7	772	96,0	64,666	28,909
WEEK 25	Negative (ER and PgR negative)	799	92,5	771	96,5	72,853	25,670	786	91,6	748	95,2	71,431	25,288
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	763	89,1	77,636	24,314	854	99,5	760	89,0	75,497	24,547
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	715	89,3	81,154	22,323	781	91,0	691	88,5	76,142	24,961
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	690	87,7	81,610	22,525	763	88,9	672	88,1	79,117	22,854
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	674	89,5	83,296	21,899	735	85,7	650	88,4	80,803	22,821
BASELINE	Positive (ER and/or PgR positive)	947	100,0	911	96,2	78,287	23,104	965	100,0	929	96,3	77,966	23,833
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	702	92,4	67,114	27,965	785	81,3	739	94,1	66,971	27,073
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	829	95,0	65,638	28,274	921	95,4	858	93,2	65,236	28,403
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	806	95,3	71,123	26,324	902	93,5	846	93,8	71,181	26,577
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	804	85,7	75,677	24,836	957	99,2	860	89,9	73,398	26,684
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	760	88,2	78,045	23,470	907	94,0	774	85,3	76,647	24,845
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	731	86,4	78,671	24,732	875	90,7	747	85,4	78,153	25,140

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	708	86,6	80,026	24,664	821	85,1	692	84,3	79,070	24,668
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	79,877	24,218	260	100,0	250	96,2	78,133	23,799
END OF ANTHRACYCLINE	USA/Canada	109	41,1	101	92,7	72,855	22,536	111	42,7	104	93,7	64,824	27,058
WEEK 13	USA/Canada	242	91,3	228	94,2	65,083	28,282	236	90,8	224	94,9	63,318	28,802
WEEK 25	USA/Canada	234	88,3	224	95,7	69,953	25,636	230	88,5	217	94,3	69,688	25,296
END OF TREATMENT	USA/Canada	259	97,7	217	83,8	76,037	25,783	255	98,1	228	89,4	73,867	26,497
FU MONTH 18	USA/Canada	238	89,8	193	81,1	78,699	22,905	231	88,8	178	77,1	76,732	25,714
FU MONTH 24	USA/Canada	231	87,2	186	80,5	77,599	25,453	224	86,2	176	78,6	79,293	23,596
FU MONTH 36	USA/Canada	223	84,2	179	80,3	80,261	24,711	205	78,8	153	74,6	82,099	23,282
BASELINE	Western Europe	827	100,0	776	93,8	79,049	25,007	822	100,0	776	94,4	78,963	25,619
END OF ANTHRACYCLINE	Western Europe	732	88,5	664	90,7	65,462	29,839	728	88,6	662	90,9	65,177	29,788
WEEK 13	Western Europe	764	92,4	698	91,4	65,954	29,408	778	94,6	702	90,2	63,988	30,318
WEEK 25	Western Europe	738	89,2	688	93,2	71,972	27,382	750	91,2	676	90,1	72,132	27,934
END OF TREATMENT	Western Europe	821	99,3	686	83,6	75,968	26,350	817	99,4	699	85,6	74,507	26,977
FU MONTH 18	Western Europe	754	91,2	642	85,1	79,534	24,934	764	92,9	623	81,5	76,146	26,494
FU MONTH 24	Western Europe	739	89,4	604	81,7	80,749	24,974	747	90,9	615	82,3	78,699	24,716
FU MONTH 36	Western Europe	713	86,2	605	84,9	81,680	25,030	712	86,6	591	83,0	80,288	25,221
BASELINE	Asia Pacific	490	100,0	485	99,0	79,221	20,658	512	100,0	507	99,0	78,435	21,090
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	373	97,9	68,648	25,050	397	77,5	389	98,0	68,595	26,295
WEEK 13	Asia Pacific	466	95,1	464	99,6	67,601	26,336	493	96,3	492	99,8	67,734	25,906
WEEK 25	Asia Pacific	461	94,1	461	100,0	72,596	24,310	492	96,1	488	99,2	72,404	22,678

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	76,760	21,796	512	100,0	488	95,3	75,290	23,119
FU MONTH 18	Asia Pacific	459	93,7	450	98,0	78,981	20,974	485	94,7	473	97,5	77,484	21,552
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	79,397	21,312	470	91,8	447	95,1	78,617	22,488
FU MONTH 36	Asia Pacific	437	89,2	418	95,7	80,841	21,022	453	88,5	432	95,4	79,115	21,232
BASELINE	Latin America	43	100,0	43	100,0	85,465	18,193	47	100,0	46	97,9	79,710	19,217
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	78,161	25,917	32	68,1	32	100,0	72,396	24,267
WEEK 13	Latin America	40	93,0	40	100,0	78,958	22,248	44	93,6	44	100,0	67,235	30,308
WEEK 25	Latin America	39	90,7	39	100,0	80,769	17,433	44	93,6	44	100,0	72,348	24,693
END OF TREATMENT	Latin America	42	97,7	38	90,5	89,254	15,966	45	95,7	42	93,3	78,175	22,312
FU MONTH 18	Latin America	41	95,3	37	90,2	91,216	13,742	42	89,4	40	95,2	78,542	19,961
FU MONTH 24	Latin America	40	93,0	36	90,0	92,824	15,450	41	87,2	39	95,1	83,761	18,727
FU MONTH 36	Latin America	38	88,4	34	89,5	93,137	12,045	37	78,7	36	97,3	82,639	18,406
BASELINE	Other	186	100,0	182	97,8	72,070	27,152	182	100,0	181	99,5	72,376	23,398
END OF ANTHRACYCLINE	Other	181	97,3	170	93,9	66,176	29,843	178	97,8	172	96,6	64,244	28,737
WEEK 13	Other	176	94,6	172	97,7	66,037	28,011	174	95,6	168	96,6	62,550	28,034
WEEK 25	Other	173	93,0	165	95,4	70,859	26,713	172	94,5	169	98,3	66,568	27,548
END OF TREATMENT	Other	185	99,5	162	87,6	76,903	23,938	182	100,0	163	89,6	70,876	27,173
FU MONTH 18	Other	171	91,9	153	89,5	79,557	21,238	166	91,2	151	91,0	73,179	27,854
FU MONTH 24	Other	169	90,9	154	91,1	79,600	23,915	156	85,7	142	91,0	75,939	27,774
FU MONTH 36	Other	160	86,0	146	91,3	82,591	22,762	149	81,9	130	87,2	77,500	26,931
Protocol version													
BASELINE	Protocol A	1240	100,0	1191	96,0	79,786	23,469	1246	100,0	1200	96,3	78,009	24,168

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	910	92,5	68,266	28,006	988	79,3	927	93,8	65,762	28,909
WEEK 13	Protocol A	1155	93,1	1106	95,8	67,910	27,941	1180	94,7	1108	93,9	64,385	29,166
WEEK 25	Protocol A	1125	90,7	1081	96,1	73,091	25,698	1157	92,9	1087	93,9	71,903	25,627
END OF TREATMENT	Protocol A	1229	99,1	1069	87,0	78,472	24,228	1236	99,2	1112	90,0	74,855	25,636
FU MONTH 18	Protocol A	1142	92,1	1020	89,3	80,539	23,433	1156	92,8	998	86,3	76,926	24,969
FU MONTH 24	Protocol A	1124	90,6	989	88,0	81,716	23,529	1127	90,4	976	86,6	79,215	23,665
FU MONTH 36	Protocol A	1087	87,7	973	89,5	83,131	23,194	1069	85,8	927	86,7	80,481	23,488
BASELINE	Protocol Amendment B	571	100,0	553	96,8	76,201	24,801	577	100,0	560	97,1	78,090	23,022
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	427	95,3	65,164	28,158	458	79,4	432	94,3	67,078	27,260
WEEK 13	Protocol Amendment B	533	93,3	496	93,1	63,810	28,355	545	94,5	522	95,8	66,198	27,465
WEEK 25	Protocol Amendment B	520	91,1	496	95,4	69,523	26,548	531	92,0	507	95,5	70,003	26,678
END OF TREATMENT	Protocol Amendment B	565	98,9	498	88,1	72,680	24,933	575	99,7	508	88,3	73,349	25,889
FU MONTH 18	Protocol Amendment B	521	91,2	455	87,3	77,338	21,745	532	92,2	467	87,8	75,303	24,719
FU MONTH 24	Protocol Amendment B	509	89,1	432	84,9	76,395	23,778	511	88,6	443	86,7	77,276	24,950
FU MONTH 36	Protocol Amendment B	484	84,8	409	84,5	78,029	23,543	487	84,4	415	85,2	78,635	24,458
Nodal status													
BASELINE	0 positive nodes	308	100,0	295	95,8	82,392	23,443	321	100,0	309	96,3	80,762	22,348
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	208	93,3	69,431	27,365	229	71,3	216	94,3	66,191	27,862
WEEK 13	0 positive nodes	294	95,5	277	94,2	69,164	27,309	303	94,4	292	96,4	65,554	28,206
WEEK 25	0 positive nodes	287	93,2	280	97,6	74,335	25,218	294	91,6	282	95,9	72,606	24,356
END OF TREATMENT	0 positive nodes	305	99,0	269	88,2	81,423	22,463	318	99,1	291	91,5	76,327	24,826
FU MONTH 18	0 positive nodes	292	94,8	262	89,7	82,952	22,252	298	92,8	264	88,6	78,051	24,441

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	250	86,2	84,689	21,127	295	91,9	262	88,8	80,821	21,994
FU MONTH 36	0 positive nodes	283	91,9	256	90,5	85,688	22,092	290	90,3	262	90,3	81,616	22,981
BASELINE	>= 1 positive nodes	1503	100,0	1449	96,4	77,887	23,989	1502	100,0	1451	96,6	77,454	24,069
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1129	93,4	66,878	28,205	1217	81,0	1143	93,9	66,178	28,503
WEEK 13	>= 1 positive nodes	1394	92,7	1325	95,1	66,113	28,274	1422	94,7	1338	94,1	64,838	28,738
WEEK 25	>= 1 positive nodes	1358	90,4	1297	95,5	71,458	26,162	1394	92,8	1312	94,1	71,018	26,307
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1298	87,2	75,638	24,907	1493	99,4	1329	89,0	73,957	25,898
FU MONTH 18	>= 1 positive nodes	1371	91,2	1213	88,5	78,817	23,060	1390	92,5	1201	86,4	76,048	24,986
FU MONTH 24	>= 1 positive nodes	1343	89,4	1171	87,2	79,118	24,137	1343	89,4	1157	86,2	78,109	24,510
FU MONTH 36	>= 1 positive nodes	1288	85,7	1126	87,4	80,696	23,605	1266	84,3	1080	85,3	79,496	23,985
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	845	96,8	77,564	23,957	885	100,0	862	97,4	76,940	24,616
END OF ANTHRACYCLINE	Premenopausal	708	81,1	675	95,3	66,864	27,336	726	82,0	692	95,3	65,763	27,841
WEEK 13	Premenopausal	841	96,3	804	95,6	63,875	28,659	852	96,3	807	94,7	63,689	28,296
WEEK 25	Premenopausal	825	94,5	797	96,6	69,315	26,782	838	94,7	797	95,1	69,939	26,180
END OF TREATMENT	Premenopausal	866	99,2	760	87,8	75,285	24,041	881	99,5	809	91,8	73,651	26,153
FU MONTH 18	Premenopausal	819	93,8	716	87,4	77,945	23,497	835	94,4	736	88,1	74,713	25,211
FU MONTH 24	Premenopausal	803	92,0	701	87,3	78,808	24,354	807	91,2	705	87,4	77,380	24,764

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	668	87,3	80,963	23,144	773	87,3	665	86,0	79,474	24,286
BASELINE	Postmenopausal	933	100,0	894	95,8	79,686	23,906	929	100,0	890	95,8	79,101	22,975
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	657	91,4	67,660	28,834	711	76,5	660	92,8	66,599	29,002
WEEK 13	Postmenopausal	842	90,2	794	94,3	69,336	27,333	864	93,0	816	94,4	66,306	28,864
WEEK 25	Postmenopausal	815	87,4	775	95,1	74,634	24,864	841	90,5	791	94,1	72,651	25,657
END OF TREATMENT	Postmenopausal	923	98,9	803	87,0	77,882	25,062	921	99,1	804	87,3	75,155	25,260
FU MONTH 18	Postmenopausal	839	89,9	756	90,1	81,066	22,391	844	90,9	723	85,7	78,158	24,397
FU MONTH 24	Postmenopausal	825	88,4	716	86,8	81,297	23,066	823	88,6	709	86,1	79,882	23,289
FU MONTH 36	Postmenopausal	801	85,9	710	88,6	82,195	23,684	776	83,5	673	86,7	80,395	23,269
BASELINE	Unknown/Missing	5	100,0	5	100,0	76,667	27,889	9	100,0	8	88,9	77,431	22,588
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	72,222	32,155	9	100,0	7	77,8	67,857	27,398
WEEK 13	Unknown/Missing	5	100,0	4	80,0	87,500	15,957	9	100,0	7	77,8	55,952	36,866
WEEK 25	Unknown/Missing	5	100,0	5	100,0	81,667	36,515	9	100,0	6	66,7	73,611	34,728
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	81,250	26,680	9	100,0	7	77,8	70,238	27,995
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	81,481	16,973	9	100,0	6	66,7	73,611	34,326
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	91,667	16,667	8	88,9	5	62,5	71,667	32,059
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	89,583	15,775	7	77,8	4	57,1	70,833	33,679
Age II													
BASELINE	< 65	1581	100,0	1529	96,7	77,881	24,266	1604	100,0	1553	96,8	77,429	24,037
END OF ANTHRACYCLINE	< 65	1268	80,2	1192	94,0	67,261	27,933	1287	80,2	1217	94,6	65,672	28,346
WEEK 13	< 65	1497	94,7	1422	95,0	66,096	28,174	1529	95,3	1448	94,7	64,004	28,686

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1400	95,6	71,677	25,956	1501	93,6	1423	94,8	70,694	25,860
END OF TREATMENT	< 65	1569	99,2	1380	88,0	76,393	24,443	1596	99,5	1439	90,2	73,477	25,921
FU MONTH 18	< 65	1474	93,2	1304	88,5	79,152	23,217	1497	93,3	1309	87,4	75,845	25,121
FU MONTH 24	< 65	1446	91,5	1254	86,7	79,840	23,809	1450	90,4	1262	87,0	78,244	24,130
FU MONTH 36	< 65	1390	87,9	1225	88,1	81,354	23,440	1383	86,2	1196	86,5	79,615	23,918
BASELINE	>= 65	230	100,0	215	93,5	84,109	20,823	219	100,0	207	94,5	82,582	21,481
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	67,395	29,370	159	72,6	142	89,3	70,540	28,509
WEEK 13	>= 65	191	83,0	180	94,2	70,941	27,430	196	89,5	182	92,9	72,619	27,121
WEEK 25	>= 65	181	78,7	177	97,8	74,278	26,415	187	85,4	171	91,4	76,332	26,435
END OF TREATMENT	>= 65	225	97,8	187	83,1	78,387	25,686	215	98,2	181	84,2	81,584	22,856
FU MONTH 18	>= 65	189	82,2	171	90,5	82,602	20,762	191	87,2	156	81,7	81,143	22,403
FU MONTH 24	>= 65	187	81,3	167	89,3	82,036	23,049	188	85,8	157	83,5	81,546	23,553
FU MONTH 36	>= 65	181	78,7	157	86,7	83,705	23,100	173	79,0	146	84,4	82,325	22,729
Histological grade													
BASELINE	Grade 1	32	100,0	30	93,8	78,333	22,701	24	100,0	24	100,0	81,944	23,399
END OF ANTHRACYCLINE	Grade 1	18	56,3	16	88,9	63,021	34,016	17	70,8	16	94,1	67,188	29,419
WEEK 13	Grade 1	31	96,9	30	96,8	63,056	34,719	23	95,8	22	95,7	71,970	23,925
WEEK 25	Grade 1	31	96,9	29	93,5	70,690	26,127	23	95,8	22	95,7	71,591	25,284
END OF TREATMENT	Grade 1	31	96,9	27	87,1	74,691	21,985	24	100,0	22	91,7	71,591	28,366
FU MONTH 18	Grade 1	30	93,8	27	90,0	80,247	23,587	23	95,8	22	95,7	72,727	23,874
FU MONTH 24	Grade 1	28	87,5	27	96,4	80,556	24,019	23	95,8	21	91,3	79,101	25,619
FU MONTH 36	Grade 1	27	84,4	26	96,3	83,333	27,487	22	91,7	20	90,9	79,583	26,693
BASELINE	Grade 2	552	100,0	534	96,7	78,844	22,452	557	100,0	540	96,9	78,447	22,822
END OF ANTHRACYCLINE	Grade 2	445	80,6	422	94,8	68,516	27,796	446	80,1	422	94,6	65,521	28,552

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	67,520	27,703	524	94,1	503	96,0	65,236	28,015
WEEK 25	Grade 2	494	89,5	476	96,4	72,216	25,195	515	92,5	493	95,7	72,718	24,150
END OF TREATMENT	Grade 2	548	99,3	484	88,3	77,451	24,000	553	99,3	494	89,3	74,837	24,088
FU MONTH 18	Grade 2	507	91,8	453	89,3	81,022	21,212	517	92,8	446	86,3	76,719	24,900
FU MONTH 24	Grade 2	501	90,8	447	89,2	81,059	23,126	500	89,8	431	86,2	79,054	23,875
FU MONTH 36	Grade 2	487	88,2	435	89,3	82,989	22,611	476	85,5	413	86,8	79,910	23,032
BASELINE	Grade 3	1161	100,0	1117	96,2	78,362	24,865	1173	100,0	1128	96,2	78,034	24,242
END OF ANTHRACYCLINE	Grade 3	918	79,1	851	92,7	66,725	28,092	919	78,3	859	93,5	66,479	28,497
WEEK 13	Grade 3	1088	93,7	1026	94,3	66,401	27,876	1114	95,0	1045	93,8	64,710	28,984
WEEK 25	Grade 3	1059	91,2	1014	95,8	71,830	26,246	1087	92,7	1018	93,7	70,555	26,949
END OF TREATMENT	Grade 3	1150	99,1	995	86,5	76,435	24,714	1165	99,3	1044	89,6	74,423	26,349
FU MONTH 18	Grade 3	1067	91,9	941	88,2	79,077	23,313	1085	92,5	938	86,5	76,561	24,957
FU MONTH 24	Grade 3	1046	90,1	893	85,4	79,706	23,800	1053	89,8	912	86,6	78,506	24,201
FU MONTH 36	Grade 3	1002	86,3	869	86,7	81,013	23,544	999	85,2	858	85,9	80,025	24,208
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	82,231	20,201	69	100,0	68	98,6	73,407	24,146
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	67,535	28,777	64	92,8	62	96,9	66,263	26,067
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	65,437	32,305	64	92,8	60	93,8	64,583	29,577
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	72,989	28,965	63	91,3	61	96,8	72,131	23,809
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	74,180	28,452	69	100,0	60	87,0	70,972	26,904
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	75,154	29,607	63	91,3	59	93,7	73,023	24,435

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	78,395	27,354	62	89,9	55	88,7	76,667	23,646
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	79,487	25,483	59	85,5	51	86,4	78,105	22,358
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	698	95,9	85,128	19,796	715	100,0	677	94,7	84,679	20,572
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	544	91,9	71,472	27,272	572	80,0	521	91,1	69,636	27,567
WEEK 13	Breast conserving surgery	677	93,0	637	94,1	68,803	28,457	673	94,1	630	93,6	67,928	28,096
WEEK 25	Breast conserving surgery	665	91,3	635	95,5	75,577	25,242	654	91,5	612	93,6	74,905	25,020
END OF TREATMENT	Breast conserving surgery	722	99,2	620	85,9	81,062	22,739	711	99,4	618	86,9	78,731	24,307
FU MONTH 18	Breast conserving surgery	678	93,1	593	87,5	84,219	20,666	659	92,2	554	84,1	81,929	22,643
FU MONTH 24	Breast conserving surgery	666	91,5	569	85,4	84,368	21,128	644	90,1	553	85,9	83,941	21,021
FU MONTH 36	Breast conserving surgery	651	89,4	556	85,4	86,226	20,365	616	86,2	534	86,7	84,675	20,556
BASELINE	Mastectomy	1083	100,0	1046	96,6	74,325	25,468	1107	100,0	1082	97,7	73,865	24,740
END OF ANTHRACYCLINE	Mastectomy	840	77,6	793	94,4	64,397	28,283	873	78,9	837	95,9	64,008	28,709
WEEK 13	Mastectomy	1011	93,4	965	95,5	65,213	27,827	1051	94,9	999	95,1	63,063	28,821
WEEK 25	Mastectomy	980	90,5	942	96,1	69,536	26,254	1033	93,3	981	95,0	69,020	26,307
END OF TREATMENT	Mastectomy	1072	99,0	947	88,3	73,730	25,332	1099	99,3	1001	91,1	71,681	26,209
FU MONTH 18	Mastectomy	985	91,0	882	89,5	76,414	23,894	1028	92,9	910	88,5	73,022	25,600
FU MONTH 24	Mastectomy	967	89,3	852	88,1	77,246	24,916	993	89,7	865	87,1	75,177	25,276

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	826	89,8	78,521	24,780	939	84,8	808	86,0	76,760	25,241
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	91,667	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	83,333	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	91,667	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	100,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	640	97,0	80,265	22,780	665	100,0	635	95,5	80,214	23,126
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	480	92,5	67,546	27,710	523	78,6	491	93,9	66,356	27,303
WEEK 13	0 - < 2 cm	620	93,9	582	93,9	66,753	28,510	631	94,9	605	95,9	66,157	28,745
WEEK 25	0 - < 2 cm	608	92,1	579	95,2	72,995	25,968	617	92,8	588	95,3	72,865	25,133
END OF TREATMENT	0 - < 2 cm	655	99,2	575	87,8	78,444	22,717	661	99,4	597	90,3	76,154	25,005
FU MONTH 18	0 - < 2 cm	617	93,5	545	88,3	81,544	21,050	624	93,8	557	89,3	78,247	24,896
FU MONTH 24	0 - < 2 cm	607	92,0	529	87,1	82,110	22,318	606	91,1	528	87,1	81,513	22,655
FU MONTH 36	0 - < 2 cm	596	90,3	521	87,4	83,755	21,659	580	87,2	503	86,7	83,024	22,167
BASELINE	>= 2 - < 5 cm	1009	100,0	968	95,9	78,444	23,984	991	100,0	961	97,0	76,757	24,289
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	750	94,1	68,111	27,769	789	79,6	742	94,0	65,319	29,329
WEEK 13	>= 2 - < 5 cm	935	92,7	893	95,5	67,189	27,361	940	94,9	885	94,1	63,977	28,713
WEEK 25	>= 2 - < 5 cm	910	90,2	876	96,3	71,829	25,611	919	92,7	860	93,6	70,229	26,419
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	865	86,7	76,358	25,013	985	99,4	870	88,3	73,413	26,120

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	823	89,2	79,401	22,904	914	92,2	778	85,1	75,307	25,092
FU MONTH 24	>= 2 - < 5 cm	905	89,7	779	86,1	79,568	23,995	889	89,7	773	87,0	76,973	24,724
FU MONTH 36	>= 2 - < 5 cm	857	84,9	758	88,4	81,376	23,757	839	84,7	723	86,2	77,851	24,614
BASELINE	>= 5 cm	139	100,0	134	96,4	72,595	28,027	165	100,0	162	98,2	77,212	23,142
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	104	92,0	60,337	30,952	132	80,0	124	93,9	70,565	26,892
WEEK 13	>= 5 cm	130	93,5	124	95,4	62,500	31,026	152	92,1	138	90,8	66,002	27,813
WEEK 25	>= 5 cm	124	89,2	119	96,0	68,347	28,345	150	90,9	144	96,0	71,528	26,563
END OF TREATMENT	>= 5 cm	138	99,3	124	89,9	70,296	28,794	163	98,8	151	92,6	73,179	26,032
FU MONTH 18	>= 5 cm	120	86,3	104	86,7	70,112	30,094	148	89,7	128	86,5	75,326	23,323
FU MONTH 24	>= 5 cm	118	84,9	110	93,2	74,091	27,310	141	85,5	116	82,3	76,724	24,684
FU MONTH 36	>= 5 cm	115	82,7	100	87,0	72,222	27,285	135	81,8	114	84,4	79,825	23,698
BASELINE	Missing	3	100,0	2	66,7	66,667	23,570	2	100,0	2	100,0	66,667	0,000
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	55,556	41,944	2	100,0	2	100,0	70,833	5,893
WEEK 13	Missing	3	100,0	3	100,0	52,778	50,231	2	100,0	2	100,0	70,833	5,893
WEEK 25	Missing	3	100,0	3	100,0	58,333	50,690	2	100,0	2	100,0	54,167	17,678
END OF TREATMENT	Missing	3	100,0	3	100,0	69,444	26,788	2	100,0	2	100,0	58,333	11,785
FU MONTH 18	Missing	3	100,0	3	100,0	86,111	12,729	2	100,0	2	100,0	62,500	29,463
FU MONTH 24	Missing	3	100,0	3	100,0	83,333	16,667	2	100,0	2	100,0	54,167	41,248
FU MONTH 36	Missing	3	100,0	3	100,0	86,111	12,729	2	100,0	2	100,0	45,833	41,248
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1310	97,3	79,595	23,270	1350	100,0	1299	96,2	79,035	23,645
END OF ANTHRACYCLINE	Yes	1103	81,9	1041	94,4	68,252	27,717	1104	81,8	1041	94,3	67,539	28,090
WEEK 13	Yes	1308	97,1	1241	94,9	66,799	28,218	1324	98,1	1243	93,9	65,925	28,525
WEEK 25	Yes	1277	94,8	1219	95,5	72,717	25,700	1302	96,4	1221	93,8	72,234	25,851

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1207	89,6	77,200	24,489	1350	100,0	1230	91,1	75,605	25,075
FU MONTH 18	Yes	1291	95,8	1137	88,1	80,433	22,693	1298	96,1	1123	86,5	77,617	24,402
FU MONTH 24	Yes	1266	94,0	1100	86,9	80,571	23,651	1260	93,3	1086	86,2	79,688	23,555
FU MONTH 36	Yes	1219	90,5	1054	86,5	82,551	22,429	1195	88,5	1027	85,9	80,853	23,426
BASELINE	No	464	100,0	434	93,5	75,794	25,712	473	100,0	461	97,5	75,217	24,045
END OF ANTHRACYCLINE	No	329	70,9	296	90,0	63,842	29,115	342	72,3	318	93,0	61,731	28,961
WEEK 13	No	380	81,9	361	95,0	66,097	27,834	401	84,8	387	96,5	61,886	28,813
WEEK 25	No	368	79,3	358	97,3	69,421	26,930	386	81,6	373	96,6	68,238	26,166
END OF TREATMENT	No	447	96,3	360	80,5	74,722	24,886	461	97,5	390	84,6	70,527	27,322
FU MONTH 18	No	372	80,2	338	90,9	76,586	23,654	390	82,5	342	87,7	72,442	26,083
FU MONTH 24	No	367	79,1	321	87,5	78,479	23,936	378	79,9	333	88,1	75,092	25,443
FU MONTH 36	No	352	75,9	328	93,2	78,633	26,112	361	76,3	315	87,3	76,834	24,765
Race													
BASELINE	White	1252	100,0	1190	95,0	78,186	25,374	1255	100,0	1203	95,9	78,076	24,830
END OF ANTHRACYCLINE	White	1010	80,7	926	91,7	65,848	29,358	1018	81,1	939	92,2	65,350	29,033
WEEK 13	White	1158	92,5	1081	93,4	65,600	28,679	1183	94,3	1090	92,1	63,675	29,664
WEEK 25	White	1120	89,5	1055	94,2	71,372	26,887	1150	91,6	1065	92,6	70,822	27,189
END OF TREATMENT	White	1238	98,9	1042	84,2	75,925	25,814	1244	99,1	1083	87,1	73,838	26,878
FU MONTH 18	White	1138	90,9	973	85,5	79,605	23,628	1152	91,8	957	83,1	76,059	26,461
FU MONTH 24	White	1115	89,1	931	83,5	80,287	24,652	1120	89,2	936	83,6	78,318	25,225
FU MONTH 36	White	1071	85,5	914	85,3	81,683	24,360	1064	84,8	889	83,6	80,181	24,873
BASELINE	Black	25	100,0	24	96,0	83,681	22,317	31	100,0	29	93,5	74,138	25,525
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	81,481	14,894	15	48,4	15	100,0	61,667	36,022
WEEK 13	Black	21	84,0	17	81,0	70,588	37,048	29	93,5	28	96,6	62,500	33,679

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	75,000	25,000	29	93,5	28	96,6	66,667	29,831
END OF TREATMENT	Black	24	96,0	22	91,7	82,197	24,973	31	100,0	28	90,3	67,857	29,460
FU MONTH 18	Black	23	92,0	17	73,9	80,392	23,188	29	93,5	24	82,8	65,625	28,796
FU MONTH 24	Black	22	88,0	18	81,8	81,481	21,305	28	90,3	23	82,1	81,522	17,218
FU MONTH 36	Black	22	88,0	18	81,8	85,185	25,654	26	83,9	20	76,9	70,417	34,250
BASELINE	Asian	477	100,0	473	99,2	78,482	20,699	484	100,0	477	98,6	78,162	21,026
END OF ANTHRACYCLINE	Asian	370	77,6	359	97,0	68,911	25,009	375	77,5	367	97,9	67,711	26,632
WEEK 13	Asian	455	95,4	450	98,9	67,543	26,400	466	96,3	465	99,8	67,485	25,385
WEEK 25	Asian	450	94,3	449	99,8	72,173	24,337	465	96,1	459	98,7	72,386	22,675
END OF TREATMENT	Asian	475	99,6	452	95,2	76,659	21,862	484	100,0	461	95,2	75,452	22,880
FU MONTH 18	Asian	447	93,7	432	96,6	78,337	21,741	461	95,2	443	96,1	77,163	21,239
FU MONTH 24	Asian	442	92,7	423	95,7	78,618	21,746	445	91,9	419	94,2	78,302	22,177
FU MONTH 36	Asian	424	88,9	402	94,8	80,245	21,373	425	87,8	398	93,6	79,313	20,825
BASELINE	Other	52	100,0	52	100,0	88,301	14,876	51	100,0	50	98,0	78,000	23,192
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	84,430	16,230	36	70,6	36	100,0	73,148	24,810
WEEK 13	Other	49	94,2	49	100,0	79,762	22,885	45	88,2	45	100,0	70,370	30,075
WEEK 25	Other	49	94,2	49	100,0	81,973	19,569	42	82,4	40	95,2	73,333	25,473
END OF TREATMENT	Other	52	100,0	47	90,4	89,539	17,330	50	98,0	47	94,0	80,142	21,462
FU MONTH 18	Other	50	96,2	48	96,0	89,410	16,555	44	86,3	39	88,6	82,265	19,325
FU MONTH 24	Other	49	94,2	45	91,8	90,926	17,392	43	84,3	39	90,7	86,111	17,660
FU MONTH 36	Other	49	94,2	43	87,8	91,085	18,221	39	76,5	33	84,6	84,343	19,516
BASELINE	Missing	5	100,0	5	100,0	80,000	29,814	2	100,0	1	50,0	83,333	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	58,333	33,850	2	100,0	2	100,0	83,333	23,570
WEEK 13	Missing	5	100,0	5	100,0	68,333	44,253	2	100,0	2	100,0	95,833	5,893

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	70,000	31,513	2	100,0	2	100,0	100,000	0,000
END OF TREATMENT	Missing	5	100,0	4	80,0	75,000	26,352	2	100,0	1	50,0	83,333	NE
FU MONTH 18	Missing	5	100,0	5	100,0	76,667	32,489	2	100,0	2	100,0	91,667	11,785
FU MONTH 24	Missing	5	100,0	4	80,0	64,583	45,325	2	100,0	2	100,0	100,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	86,667	19,185	2	100,0	2	100,0	100,000	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC06_SG.xls
11AUG2020 15:57

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1700	93,9	18,529	23,111	1823	100,0	1715	94,1	20,155	23,864
END OF ANTHRACYCLINE	n/a	1432	79,1	1300	90,8	15,141	20,368	1446	79,3	1332	92,1	16,116	21,136
WEEK 13	n/a	1688	93,2	1549	91,8	13,138	18,651	1725	94,6	1590	92,2	14,203	19,816
WEEK 25	n/a	1645	90,8	1522	92,5	16,721	21,550	1688	92,6	1542	91,4	17,856	21,988
END OF TREATMENT	n/a	1794	99,1	1511	84,2	18,321	21,900	1811	99,3	1569	86,6	20,130	23,503
FU MONTH 18	n/a	1663	91,8	1423	85,6	20,965	23,770	1688	92,6	1420	84,1	21,526	23,864
FU MONTH 24	n/a	1633	90,2	1368	83,8	21,686	23,733	1638	89,9	1375	83,9	21,964	23,776
FU MONTH 36	n/a	1571	86,7	1328	84,5	21,298	24,358	1556	85,4	1298	83,4	22,188	24,346
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	47	92,2	18,085	22,476	43	100,0	39	90,7	28,205	22,016
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	27	75,0	12,346	17,042	26	60,5	25	96,2	25,333	25,513
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	10,317	19,110	40	93,0	39	97,5	21,368	23,242
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	38	86,4	14,474	22,980	38	88,4	35	92,1	27,143	25,593
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	40	78,4	21,667	23,930	42	97,7	35	83,3	31,429	26,436
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	38	82,6	23,246	23,741	39	90,7	32	82,1	31,250	24,593

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	37	80,4	26,577	26,776	39	90,7	29	74,4	32,759	26,533
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	39	84,8	31,624	31,250	39	90,7	34	87,2	31,863	26,707
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	236	91,8	17,585	22,916	278	100,0	261	93,9	17,114	22,475
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	170	90,9	14,314	19,553	203	73,0	184	90,6	13,587	18,510
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	221	89,1	11,765	17,548	263	94,6	246	93,5	13,482	18,688
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	226	93,0	15,708	21,089	256	92,1	237	92,6	15,893	20,311
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	216	85,0	16,821	20,396	276	99,3	247	89,5	18,219	22,057
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	210	85,4	19,524	23,396	259	93,2	226	87,3	18,510	22,886
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	199	81,6	19,765	23,335	256	92,1	224	87,5	19,940	22,910
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	203	85,7	18,227	21,342	251	90,3	219	87,3	19,863	22,855
BASELINE	1-3 positive nodes	907	100,0	862	95,0	19,683	23,746	900	100,0	842	93,6	20,091	23,355
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	648	90,9	16,538	21,820	707	78,6	655	92,6	16,387	20,985
WEEK 13	1-3 positive nodes	847	93,4	780	92,1	14,466	19,326	854	94,9	782	91,6	13,896	19,747
WEEK 25	1-3 positive nodes	825	91,0	759	92,0	18,665	22,375	836	92,9	758	90,7	17,502	21,520
END OF TREATMENT	1-3 positive nodes	899	99,1	755	84,0	19,073	22,046	897	99,7	782	87,2	19,757	23,099
FU MONTH 18	1-3 positive nodes	838	92,4	711	84,8	22,504	24,798	852	94,7	713	83,7	21,529	23,812

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	698	84,4	22,827	24,259	830	92,2	698	84,1	22,517	23,797
FU MONTH 36	1-3 positive nodes	804	88,6	679	84,5	22,459	24,823	794	88,2	637	80,2	22,266	24,193
BASELINE	>= 4 positive nodes	596	100,0	555	93,1	17,177	22,195	602	100,0	573	95,2	21,088	25,161
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	455	91,7	13,626	18,541	510	84,7	468	91,8	16,239	21,946
WEEK 13	>= 4 positive nodes	547	91,8	506	92,5	11,924	17,908	568	94,4	523	92,1	14,468	20,109
WEEK 25	>= 4 positive nodes	533	89,4	499	93,6	14,395	20,106	558	92,7	512	91,8	18,652	23,007
END OF TREATMENT	>= 4 positive nodes	590	99,0	500	84,7	17,567	22,127	596	99,0	505	84,7	20,858	24,409
FU MONTH 18	>= 4 positive nodes	533	89,4	464	87,1	19,073	22,171	538	89,4	449	83,5	22,346	24,204
FU MONTH 24	>= 4 positive nodes	516	86,6	434	84,1	20,315	22,685	513	85,2	424	82,7	21,384	23,848
FU MONTH 36	>= 4 positive nodes	484	81,2	407	84,1	19,902	23,940	472	78,4	408	86,4	22,508	25,015
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1353	94,0	18,564	23,239	1448	100,0	1367	94,4	20,044	23,848
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1299	90,9	15,127	20,370	1444	99,7	1332	92,2	16,116	21,136
WEEK 13	Anthracycline containing regimen	1347	93,6	1244	92,4	13,063	18,664	1374	94,9	1266	92,1	14,284	19,418
WEEK 25	Anthracycline containing regimen	1311	91,1	1207	92,1	17,039	21,465	1346	93,0	1231	91,5	18,332	22,151
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1211	84,7	18,676	22,115	1444	99,7	1259	87,2	20,267	23,416

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1134	85,3	21,002	23,779	1340	92,5	1138	84,9	21,368	23,830
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1098	84,1	21,706	23,931	1308	90,3	1099	84,0	21,975	23,819
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1060	84,2	21,258	24,140	1244	85,9	1044	83,9	22,350	24,374
BASELINE	Non-anthracycline containing regimen	372	100,0	347	93,3	18,396	22,637	375	100,0	348	92,8	20,594	23,952
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	1	33,3	33,333	NE	2	0,5	0	0,0	NE	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	305	89,4	13,443	18,624	351	93,6	324	92,3	13,889	21,329
WEEK 25	Non-anthracycline containing regimen	334	89,8	315	94,3	15,503	21,866	342	91,2	311	90,9	15,970	21,261
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	300	82,2	16,889	20,983	367	97,9	310	84,5	19,570	23,885
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	289	86,5	20,819	23,775	348	92,8	282	81,0	22,163	24,034
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	270	82,6	21,605	22,955	330	88,0	276	83,6	21,920	23,647
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	268	85,9	21,455	25,251	312	83,2	254	81,4	21,522	24,269
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	811	93,9	16,954	22,512	858	100,0	812	94,6	18,144	22,874
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	613	91,2	12,806	18,973	661	77,0	607	91,8	14,305	20,196
WEEK 13	Negative (ER and PgR negative)	815	94,3	744	91,3	11,806	17,928	804	93,7	751	93,4	13,160	18,745
WEEK 25	Negative (ER and PgR negative)	799	92,5	741	92,7	15,250	21,061	786	91,6	726	92,4	16,437	21,512
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	728	85,0	16,621	21,035	854	99,5	736	86,2	18,705	22,729
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	688	85,9	19,404	23,505	781	91,0	669	85,7	20,628	23,243
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	665	84,5	19,574	23,174	763	88,9	651	85,3	20,789	23,617
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	645	85,7	19,767	23,695	735	85,7	626	85,2	20,714	23,768
BASELINE	Positive (ER and/or PgR positive)	947	100,0	889	93,9	19,966	23,565	965	100,0	903	93,6	21,964	24,592
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	687	90,4	17,225	21,336	785	81,3	725	92,4	17,632	21,790
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	805	92,2	14,369	19,224	921	95,4	839	91,1	15,137	20,694
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	781	92,3	18,118	21,927	902	93,5	816	90,5	19,118	22,340
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	783	83,5	19,902	22,573	957	99,2	833	87,0	21,389	24,110
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	735	85,3	22,426	23,938	907	94,0	751	82,8	22,326	24,392
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	703	83,1	23,684	24,096	875	90,7	724	82,7	23,020	23,884

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	683	83,5	22,743	24,900	821	85,1	672	81,9	23,562	24,811
Geographical region II													
BASELINE	USA/Canada	265	100,0	254	95,8	22,703	24,410	260	100,0	252	96,9	24,272	25,215
END OF ANTHRACYCLINE	USA/Canada	109	41,1	101	92,7	22,442	23,622	111	42,7	103	92,8	15,534	18,415
WEEK 13	USA/Canada	242	91,3	224	92,6	16,220	19,197	236	90,8	220	93,2	16,742	21,634
WEEK 25	USA/Canada	234	88,3	220	94,0	22,727	23,595	230	88,5	212	92,2	21,855	22,874
END OF TREATMENT	USA/Canada	259	97,7	210	81,1	22,619	22,002	255	98,1	220	86,3	26,439	25,617
FU MONTH 18	USA/Canada	238	89,8	190	79,8	26,316	22,233	231	88,8	175	75,8	28,190	24,802
FU MONTH 24	USA/Canada	231	87,2	183	79,2	27,322	23,053	224	86,2	168	75,0	27,877	24,162
FU MONTH 36	USA/Canada	223	84,2	177	79,4	26,083	25,236	205	78,8	149	72,7	29,083	25,124
BASELINE	Western Europe	827	100,0	749	90,6	22,808	25,084	822	100,0	738	89,8	25,474	25,973
END OF ANTHRACYCLINE	Western Europe	732	88,5	638	87,2	18,443	21,222	728	88,6	642	88,2	20,067	22,711
WEEK 13	Western Europe	764	92,4	661	86,5	16,667	20,392	778	94,6	678	87,1	17,453	20,682
WEEK 25	Western Europe	738	89,2	650	88,1	21,718	23,253	750	91,2	639	85,2	23,891	23,169
END OF TREATMENT	Western Europe	821	99,3	647	78,8	24,575	23,836	817	99,4	662	81,0	25,629	23,964
FU MONTH 18	Western Europe	754	91,2	601	79,7	28,258	25,543	764	92,9	590	77,2	27,994	24,784
FU MONTH 24	Western Europe	739	89,4	567	76,7	29,130	25,073	747	90,9	583	78,0	28,788	24,713
FU MONTH 36	Western Europe	713	86,2	564	79,1	29,433	25,838	712	86,6	554	77,8	28,911	25,416
BASELINE	Asia Pacific	490	100,0	484	98,8	9,917	15,991	512	100,0	505	98,6	12,211	18,319
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	370	97,1	7,072	14,214	397	77,5	388	97,7	9,665	17,538
WEEK 13	Asia Pacific	466	95,1	462	99,1	6,277	12,576	493	96,3	489	99,2	8,248	16,186
WEEK 25	Asia Pacific	461	94,1	457	99,1	7,476	13,809	492	96,1	485	98,6	9,244	16,629

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	461	94,7	8,134	14,438	512	100,0	488	95,3	10,690	17,780
FU MONTH 18	Asia Pacific	459	93,7	449	97,8	9,391	15,359	485	94,7	469	96,7	11,905	18,129
FU MONTH 24	Asia Pacific	454	92,7	437	96,3	9,916	15,870	470	91,8	445	94,7	12,247	18,084
FU MONTH 36	Asia Pacific	437	89,2	414	94,7	8,293	14,287	453	88,5	430	94,9	12,093	18,165
BASELINE	Latin America	43	100,0	39	90,7	19,658	24,445	47	100,0	43	91,5	17,054	17,247
END OF ANTHRACYCLINE	Latin America	29	67,4	27	93,1	12,346	21,972	32	68,1	29	90,6	11,494	15,497
WEEK 13	Latin America	40	93,0	37	92,5	13,063	21,565	44	93,6	42	95,5	13,492	18,123
WEEK 25	Latin America	39	90,7	37	94,9	14,865	23,169	44	93,6	42	95,5	11,905	18,140
END OF TREATMENT	Latin America	42	97,7	36	85,7	16,667	22,537	45	95,7	40	88,9	16,667	19,971
FU MONTH 18	Latin America	41	95,3	36	87,8	19,907	30,814	42	89,4	39	92,9	15,812	19,477
FU MONTH 24	Latin America	40	93,0	34	85,0	21,078	27,002	41	87,2	39	95,1	11,966	18,317
FU MONTH 36	Latin America	38	88,4	33	86,8	17,677	25,324	37	78,7	36	97,3	15,741	21,061
BASELINE	Other	186	100,0	174	93,5	17,720	22,249	182	100,0	177	97,3	15,537	20,840
END OF ANTHRACYCLINE	Other	181	97,3	164	90,6	16,463	21,049	178	97,8	170	95,5	17,059	21,295
WEEK 13	Other	176	94,6	165	93,8	14,040	19,123	174	95,6	161	92,5	15,321	20,067
WEEK 25	Other	173	93,0	158	91,3	14,979	20,101	172	94,5	164	95,3	16,159	22,187
END OF TREATMENT	Other	185	99,5	157	84,9	17,091	20,408	182	100,0	159	87,4	18,344	25,171
FU MONTH 18	Other	171	91,9	147	86,0	19,841	23,678	166	91,2	147	88,6	19,841	25,309
FU MONTH 24	Other	169	90,9	147	87,0	21,088	24,233	156	85,7	140	89,7	20,119	24,930
FU MONTH 36	Other	160	86,0	140	87,5	21,786	24,395	149	81,9	129	86,6	20,801	25,518
Protocol version													
BASELINE	Protocol A	1240	100,0	1162	93,7	19,005	23,377	1246	100,0	1173	94,1	20,801	24,190

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	885	89,9	15,650	20,617	988	79,3	906	91,7	16,188	21,135
WEEK 13	Protocol A	1155	93,1	1064	92,1	13,487	19,129	1180	94,7	1082	91,7	14,325	19,832
WEEK 25	Protocol A	1125	90,7	1043	92,7	17,018	21,854	1157	92,9	1054	91,1	18,121	22,091
END OF TREATMENT	Protocol A	1229	99,1	1027	83,6	18,906	22,072	1236	99,2	1079	87,3	20,961	24,016
FU MONTH 18	Protocol A	1142	92,1	977	85,6	21,256	24,042	1156	92,8	970	83,9	22,474	24,502
FU MONTH 24	Protocol A	1124	90,6	947	84,3	21,982	24,098	1127	90,4	947	84,0	22,562	24,442
FU MONTH 36	Protocol A	1087	87,7	931	85,6	21,858	24,512	1069	85,8	899	84,1	22,506	24,652
BASELINE	Protocol Amendment B	571	100,0	538	94,2	17,503	22,511	577	100,0	542	93,9	18,758	23,102
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	415	92,6	14,056	19,809	458	79,4	426	93,0	15,962	21,163
WEEK 13	Protocol Amendment B	533	93,3	485	91,0	12,371	17,552	545	94,5	508	93,2	13,944	19,798
WEEK 25	Protocol Amendment B	520	91,1	479	92,1	16,075	20,882	531	92,0	488	91,9	17,281	21,776
END OF TREATMENT	Protocol Amendment B	565	98,9	484	85,7	17,080	21,499	575	99,7	490	85,2	18,299	22,247
FU MONTH 18	Protocol Amendment B	521	91,2	446	85,6	20,329	23,176	532	92,2	450	84,6	19,481	22,319
FU MONTH 24	Protocol Amendment B	509	89,1	421	82,7	21,021	22,905	511	88,6	428	83,8	20,639	22,201
FU MONTH 36	Protocol Amendment B	484	84,8	397	82,0	19,983	23,973	487	84,4	399	81,9	21,470	23,657
Nodal status													
BASELINE	0 positive nodes	308	100,0	283	91,9	17,668	22,805	321	100,0	300	93,5	18,556	22,690
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	197	88,3	14,044	19,200	229	71,3	209	91,3	14,992	19,777
WEEK 13	0 positive nodes	294	95,5	263	89,5	11,534	17,776	303	94,4	285	94,1	14,561	19,517
WEEK 25	0 positive nodes	287	93,2	264	92,0	15,530	21,330	294	91,6	272	92,5	17,341	21,347
END OF TREATMENT	0 positive nodes	305	99,0	256	83,9	17,578	21,010	318	99,1	282	88,7	19,858	23,011
FU MONTH 18	0 positive nodes	292	94,8	248	84,9	20,094	23,439	298	92,8	258	86,6	20,090	23,435

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	236	81,4	20,833	23,974	295	91,9	253	85,8	21,410	23,652
FU MONTH 36	0 positive nodes	283	91,9	242	85,5	20,386	23,667	290	90,3	253	87,2	21,476	23,709
BASELINE	>= 1 positive nodes	1503	100,0	1417	94,3	18,701	23,175	1502	100,0	1415	94,2	20,495	24,099
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1103	91,2	15,337	20,572	1217	81,0	1123	92,3	16,325	21,381
WEEK 13	>= 1 positive nodes	1394	92,7	1286	92,3	13,466	18,815	1422	94,7	1305	91,8	14,125	19,887
WEEK 25	>= 1 positive nodes	1358	90,4	1258	92,6	16,971	21,596	1394	92,8	1270	91,1	17,966	22,130
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1255	84,3	18,473	22,082	1493	99,4	1287	86,2	20,189	23,618
FU MONTH 18	>= 1 positive nodes	1371	91,2	1175	85,7	21,149	23,845	1390	92,5	1162	83,6	21,845	23,957
FU MONTH 24	>= 1 positive nodes	1343	89,4	1132	84,3	21,864	23,689	1343	89,4	1122	83,5	22,089	23,812
FU MONTH 36	>= 1 positive nodes	1288	85,7	1086	84,3	21,501	24,516	1266	84,3	1045	82,5	22,360	24,506
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	836	95,8	24,203	24,328	885	100,0	854	96,5	26,366	25,250
END OF ANTHRACYCLINE	Premenopausal	708	81,1	665	93,9	19,825	21,782	726	82,0	688	94,8	21,899	22,787
WEEK 13	Premenopausal	841	96,3	790	93,9	16,646	19,598	852	96,3	799	93,8	18,085	20,778
WEEK 25	Premenopausal	825	94,5	785	95,2	21,550	22,498	838	94,7	788	94,0	22,356	23,126
END OF TREATMENT	Premenopausal	866	99,2	749	86,5	24,210	23,425	881	99,5	798	90,6	25,606	24,230
FU MONTH 18	Premenopausal	819	93,8	711	86,8	27,356	25,187	835	94,4	727	87,1	27,373	25,027
FU MONTH 24	Premenopausal	803	92,0	691	86,1	28,630	24,655	807	91,2	699	86,6	27,372	24,421

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	657	85,9	27,524	25,529	773	87,3	654	84,6	27,982	25,450
BASELINE	Postmenopausal	933	100,0	859	92,1	12,922	20,242	929	100,0	853	91,8	13,873	20,611
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	630	87,6	10,159	17,455	711	76,5	637	89,6	9,759	17,011
WEEK 13	Postmenopausal	842	90,2	755	89,7	9,382	16,664	864	93,0	783	90,6	10,153	17,644
WEEK 25	Postmenopausal	815	87,4	732	89,8	11,362	18,868	841	90,5	748	88,9	13,124	19,677
END OF TREATMENT	Postmenopausal	923	98,9	758	82,1	12,445	18,526	921	99,1	763	82,8	14,439	21,264
FU MONTH 18	Postmenopausal	839	89,9	709	84,5	14,575	20,353	844	90,9	686	81,3	15,355	20,944
FU MONTH 24	Postmenopausal	825	88,4	673	81,6	14,388	20,142	823	88,6	671	81,5	16,393	21,691
FU MONTH 36	Postmenopausal	801	85,9	667	83,3	15,167	21,445	776	83,5	640	82,5	16,198	21,522
BASELINE	Unknown/Missing	5	100,0	5	100,0	33,333	40,825	9	100,0	8	88,9	27,083	21,708
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	20,000	21,731	9	100,0	7	77,8	26,190	26,972
WEEK 13	Unknown/Missing	5	100,0	4	80,0	29,167	39,382	9	100,0	8	88,9	22,917	38,768
WEEK 25	Unknown/Missing	5	100,0	5	100,0	43,333	40,139	9	100,0	6	66,7	16,667	21,082
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	29,167	20,972	9	100,0	8	88,9	16,667	26,726
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	16,667	28,868	9	100,0	7	77,8	19,048	17,817
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	50,000	43,033	8	88,9	5	62,5	13,333	29,814
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	20,833	31,549	7	77,8	4	57,1	33,333	38,490
Age II													
BASELINE	< 65	1581	100,0	1495	94,6	19,677	23,401	1604	100,0	1522	94,9	21,649	24,216
END OF ANTHRACYCLINE	< 65	1268	80,2	1165	91,9	16,209	20,767	1287	80,2	1200	93,2	17,139	21,531
WEEK 13	< 65	1497	94,7	1383	92,4	13,931	18,828	1529	95,3	1420	92,9	14,953	20,008

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1366	93,3	17,606	21,666	1501	93,6	1384	92,2	18,882	22,235
END OF TREATMENT	< 65	1569	99,2	1345	85,7	19,380	22,092	1596	99,5	1407	88,2	21,192	23,730
FU MONTH 18	< 65	1474	93,2	1274	86,4	22,070	23,961	1497	93,3	1277	85,3	22,866	24,183
FU MONTH 24	< 65	1446	91,5	1221	84,4	22,864	23,711	1450	90,4	1234	85,1	23,406	23,965
FU MONTH 36	< 65	1390	87,9	1193	85,8	22,353	24,454	1383	86,2	1165	84,2	23,634	24,733
BASELINE	>= 65	230	100,0	205	89,1	10,163	18,916	219	100,0	193	88,1	8,377	16,764
END OF ANTHRACYCLINE	>= 65	164	71,3	135	82,3	5,926	13,424	159	72,6	132	83,0	6,818	14,111
WEEK 13	>= 65	191	83,0	166	86,9	6,526	15,653	196	89,5	170	86,7	7,941	16,931
WEEK 25	>= 65	181	78,7	156	86,2	8,974	18,874	187	85,4	158	84,5	8,861	17,309
END OF TREATMENT	>= 65	225	97,8	166	73,8	9,739	18,180	215	98,2	162	75,3	10,905	19,154
FU MONTH 18	>= 65	189	82,2	149	78,8	11,521	19,749	191	87,2	143	74,9	9,557	16,607
FU MONTH 24	>= 65	187	81,3	147	78,6	11,905	21,634	188	85,8	141	75,0	9,338	17,635
FU MONTH 36	>= 65	181	78,7	135	74,6	11,975	21,419	173	79,0	133	76,9	9,524	15,796
Histological grade													
BASELINE	Grade 1	32	100,0	29	90,6	22,989	22,009	24	100,0	24	100,0	20,833	18,553
END OF ANTHRACYCLINE	Grade 1	18	56,3	16	88,9	15,625	17,710	17	70,8	16	94,1	19,792	15,176
WEEK 13	Grade 1	31	96,9	29	93,5	15,517	19,886	23	95,8	22	95,7	12,121	14,712
WEEK 25	Grade 1	31	96,9	28	90,3	15,476	19,207	23	95,8	22	95,7	14,394	20,116
END OF TREATMENT	Grade 1	31	96,9	27	87,1	25,309	25,890	24	100,0	21	87,5	14,286	19,920
FU MONTH 18	Grade 1	30	93,8	25	83,3	28,667	27,437	23	95,8	21	91,3	18,254	22,916
FU MONTH 24	Grade 1	28	87,5	27	96,4	24,074	25,036	23	95,8	20	87,0	15,833	22,605
FU MONTH 36	Grade 1	27	84,4	26	96,3	21,154	26,059	22	91,7	19	86,4	14,035	23,083
BASELINE	Grade 2	552	100,0	520	94,2	16,827	22,032	557	100,0	531	95,3	19,994	24,280
END OF ANTHRACYCLINE	Grade 2	445	80,6	413	92,8	15,214	21,140	446	80,1	418	93,7	16,188	21,619

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	471	92,9	12,350	17,904	524	94,1	494	94,3	13,866	20,016
WEEK 25	Grade 2	494	89,5	462	93,5	16,414	21,299	515	92,5	477	92,6	17,261	21,120
END OF TREATMENT	Grade 2	548	99,3	472	86,1	17,691	21,683	553	99,3	481	87,0	20,201	23,892
FU MONTH 18	Grade 2	507	91,8	441	87,0	19,728	24,049	517	92,8	431	83,4	20,070	23,128
FU MONTH 24	Grade 2	501	90,8	433	86,4	19,823	23,385	500	89,8	418	83,6	20,933	23,280
FU MONTH 36	Grade 2	487	88,2	427	87,7	19,555	23,779	476	85,5	402	84,5	21,186	24,114
BASELINE	Grade 3	1161	100,0	1088	93,7	19,424	23,550	1173	100,0	1093	93,2	20,769	23,949
END OF ANTHRACYCLINE	Grade 3	918	79,1	824	89,8	15,574	20,246	919	78,3	837	91,1	16,408	21,044
WEEK 13	Grade 3	1088	93,7	989	90,9	13,768	19,192	1114	95,0	1016	91,2	14,649	19,756
WEEK 25	Grade 3	1059	91,2	976	92,2	17,350	21,984	1087	92,7	983	90,4	18,650	22,571
END OF TREATMENT	Grade 3	1150	99,1	951	82,7	18,857	22,167	1165	99,3	1010	86,7	20,710	23,439
FU MONTH 18	Grade 3	1067	91,9	905	84,8	21,750	23,699	1085	92,5	910	83,9	22,802	24,283
FU MONTH 24	Grade 3	1046	90,1	856	81,8	22,936	24,040	1053	89,8	882	83,8	23,148	24,044
FU MONTH 36	Grade 3	1002	86,3	825	82,3	22,687	24,840	999	85,2	826	82,7	23,426	24,640
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	15,079	23,894	69	100,0	67	97,1	11,194	18,889
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	47	92,2	6,738	14,185	64	92,8	61	95,3	10,656	19,961
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	60	96,8	7,778	13,187	64	92,8	58	90,6	10,057	20,694
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	56	91,8	8,929	14,895	63	91,3	60	95,2	10,833	18,367
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	11,749	15,319	69	100,0	57	82,6	11,404	20,930
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	52	88,1	14,103	18,782	63	91,3	58	92,1	13,506	21,049

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	52	89,7	15,385	18,916	62	89,9	55	88,7	13,030	21,443
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	50	90,9	13,333	17,496	59	85,5	51	86,4	13,072	18,948
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	672	92,3	21,404	25,613	715	100,0	653	91,3	23,073	25,132
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	525	88,7	17,937	22,263	572	80,0	511	89,3	18,167	21,691
WEEK 13	Breast conserving surgery	677	93,0	607	89,7	14,717	20,160	673	94,1	610	90,6	15,437	20,257
WEEK 25	Breast conserving surgery	665	91,3	601	90,4	17,804	22,507	654	91,5	581	88,8	20,826	22,898
END OF TREATMENT	Breast conserving surgery	722	99,2	588	81,4	20,153	22,725	711	99,4	598	84,1	22,603	24,012
FU MONTH 18	Breast conserving surgery	678	93,1	553	81,6	24,774	24,718	659	92,2	528	80,1	24,874	24,405
FU MONTH 24	Breast conserving surgery	666	91,5	535	80,3	24,548	24,558	644	90,1	527	81,8	25,585	24,634
FU MONTH 36	Breast conserving surgery	651	89,4	521	80,0	25,208	25,509	616	86,2	506	82,1	25,329	24,332
BASELINE	Mastectomy	1083	100,0	1028	94,9	16,650	21,119	1107	100,0	1061	95,8	18,379	22,881
END OF ANTHRACYCLINE	Mastectomy	840	77,6	775	92,3	13,247	18,758	873	78,9	820	93,9	14,858	20,700
WEEK 13	Mastectomy	1011	93,4	942	93,2	12,120	17,546	1051	94,9	979	93,1	13,449	19,513
WEEK 25	Mastectomy	980	90,5	921	94,0	16,015	20,885	1033	93,3	960	92,9	16,076	21,235
END OF TREATMENT	Mastectomy	1072	99,0	923	86,1	17,154	21,288	1099	99,3	971	88,4	18,606	23,066
FU MONTH 18	Mastectomy	985	91,0	870	88,3	18,544	22,833	1028	92,9	892	86,8	19,544	23,327
FU MONTH 24	Mastectomy	967	89,3	833	86,1	19,848	23,016	993	89,7	848	85,4	19,713	22,955

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	807	87,7	18,773	23,255	939	84,8	792	84,3	20,181	24,157
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	623	94,4	19,957	23,747	665	100,0	618	92,9	21,305	24,119
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	461	88,8	16,161	19,988	523	78,6	485	92,7	15,773	20,449
WEEK 13	0 - < 2 cm	620	93,9	560	90,3	13,690	18,706	631	94,9	590	93,5	14,209	19,034
WEEK 25	0 - < 2 cm	608	92,1	554	91,1	18,381	22,447	617	92,8	566	91,7	18,551	21,756
END OF TREATMENT	0 - < 2 cm	655	99,2	549	83,8	19,581	22,096	661	99,4	580	87,7	20,575	23,794
FU MONTH 18	0 - < 2 cm	617	93,5	517	83,8	23,050	24,556	624	93,8	536	85,9	23,912	24,581
FU MONTH 24	0 - < 2 cm	607	92,0	501	82,5	23,420	24,458	606	91,1	510	84,2	23,529	24,114
FU MONTH 36	0 - < 2 cm	596	90,3	494	82,9	23,414	24,634	580	87,2	484	83,4	23,313	24,268
BASELINE	>= 2 - < 5 cm	1009	100,0	942	93,4	17,728	22,652	991	100,0	939	94,8	19,666	23,985
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	735	92,2	14,580	20,629	789	79,6	725	91,9	16,345	21,845
WEEK 13	>= 2 - < 5 cm	935	92,7	865	92,5	12,909	18,951	940	94,9	865	92,0	13,719	19,934
WEEK 25	>= 2 - < 5 cm	910	90,2	848	93,2	15,507	20,861	919	92,7	833	90,6	17,267	22,025
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	841	84,3	17,103	21,265	985	99,4	843	85,6	19,711	23,259

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	802	86,9	19,722	23,349	914	92,2	758	82,9	19,723	23,237
FU MONTH 24	>= 2 - < 5 cm	905	89,7	756	83,5	20,613	23,150	889	89,7	751	84,5	20,950	23,534
FU MONTH 36	>= 2 - < 5 cm	857	84,9	734	85,6	19,846	23,916	839	84,7	702	83,7	21,462	24,347
BASELINE	>= 5 cm	139	100,0	133	95,7	17,544	23,239	165	100,0	156	94,5	18,590	22,075
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	101	89,4	14,356	20,280	132	80,0	120	90,9	15,833	19,667
WEEK 13	>= 5 cm	130	93,5	121	93,1	11,983	16,134	152	92,1	133	87,5	17,043	22,235
WEEK 25	>= 5 cm	124	89,2	117	94,4	17,379	21,927	150	90,9	141	94,0	18,558	22,808
END OF TREATMENT	>= 5 cm	138	99,3	118	85,5	21,045	24,981	163	98,8	144	88,3	20,718	23,999
FU MONTH 18	>= 5 cm	120	86,3	101	84,2	20,132	22,647	148	89,7	124	83,8	22,312	23,845
FU MONTH 24	>= 5 cm	118	84,9	108	91,5	20,988	23,939	141	85,5	112	79,4	21,726	23,765
FU MONTH 36	>= 5 cm	115	82,7	97	84,3	21,649	25,704	135	81,8	110	81,5	21,970	24,827
BASELINE	Missing	3	100,0	2	66,7	16,667	23,570	2	100,0	2	100,0	16,667	23,570
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	33,333	0,000
WEEK 13	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	33,333	0,000
WEEK 25	Missing	3	100,0	3	100,0	27,778	9,623	2	100,0	2	100,0	16,667	23,570
END OF TREATMENT	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	25,000	11,785
FU MONTH 18	Missing	3	100,0	3	100,0	22,222	19,245	2	100,0	2	100,0	16,667	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	27,778	34,694	2	100,0	2	100,0	16,667	23,570
FU MONTH 36	Missing	3	100,0	3	100,0	16,667	28,868	2	100,0	2	100,0	16,667	23,570
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1274	94,6	20,094	24,111	1350	100,0	1262	93,5	21,329	24,398
END OF ANTHRACYCLINE	Yes	1103	81,9	1013	91,8	16,617	20,976	1104	81,8	1022	92,6	16,732	21,607
WEEK 13	Yes	1308	97,1	1203	92,0	13,827	19,121	1324	98,1	1209	91,3	14,695	19,784
WEEK 25	Yes	1277	94,8	1174	91,9	17,462	21,965	1302	96,4	1176	90,3	18,807	22,290

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1162	86,3	19,621	22,508	1350	100,0	1185	87,8	21,463	23,999
FU MONTH 18	Yes	1291	95,8	1090	84,4	22,538	24,267	1298	96,1	1082	83,4	23,028	24,444
FU MONTH 24	Yes	1266	94,0	1054	83,3	23,039	24,172	1260	93,3	1045	82,9	23,477	24,394
FU MONTH 36	Yes	1219	90,5	1008	82,7	22,371	24,829	1195	88,5	989	82,8	23,711	24,844
BASELINE	No	464	100,0	426	91,8	13,850	19,094	473	100,0	453	95,8	16,887	22,005
END OF ANTHRACYCLINE	No	329	70,9	287	87,2	9,930	17,101	342	72,3	310	90,6	14,086	19,398
WEEK 13	No	380	81,9	346	91,1	10,742	16,722	401	84,8	381	95,0	12,642	19,864
WEEK 25	No	368	79,3	348	94,6	14,224	19,917	386	81,6	366	94,8	14,800	20,725
END OF TREATMENT	No	447	96,3	349	78,1	13,992	19,141	461	97,5	384	83,3	16,016	21,417
FU MONTH 18	No	372	80,2	333	89,5	15,816	21,298	390	82,5	338	86,7	16,716	21,234
FU MONTH 24	No	367	79,1	314	85,6	17,144	21,621	378	79,9	330	87,3	17,172	21,028
FU MONTH 36	No	352	75,9	320	90,9	17,917	22,516	361	76,3	309	85,6	17,314	22,018
Race													
BASELINE	White	1252	100,0	1149	91,8	22,164	24,615	1255	100,0	1164	92,7	23,855	25,232
END OF ANTHRACYCLINE	White	1010	80,7	894	88,5	18,419	21,457	1018	81,1	916	90,0	19,105	22,234
WEEK 13	White	1158	92,5	1034	89,3	16,054	19,913	1183	94,3	1058	89,4	16,997	20,751
WEEK 25	White	1120	89,5	1008	90,0	20,850	22,878	1150	91,6	1020	88,7	22,435	23,308
END OF TREATMENT	White	1238	98,9	991	80,0	23,041	23,126	1244	99,1	1039	83,5	24,687	24,622
FU MONTH 18	White	1138	90,9	923	81,1	26,327	24,760	1152	91,8	920	79,9	26,884	25,100
FU MONTH 24	White	1115	89,1	885	79,4	27,345	24,828	1120	89,2	897	80,1	27,090	24,789
FU MONTH 36	White	1071	85,5	863	80,6	27,231	25,578	1064	84,8	850	79,9	27,784	25,419
BASELINE	Black	25	100,0	24	96,0	18,750	24,233	31	100,0	29	93,5	20,690	30,425
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	25,926	35,464	15	48,4	15	100,0	18,889	22,596
WEEK 13	Black	21	84,0	17	81,0	15,686	19,957	29	93,5	27	93,1	14,815	21,845

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	18,421	24,149	29	93,5	27	93,1	17,901	26,119
END OF TREATMENT	Black	24	96,0	22	91,7	19,697	23,925	31	100,0	26	83,9	27,564	30,163
FU MONTH 18	Black	23	92,0	17	73,9	22,549	27,602	29	93,5	22	75,9	24,242	23,417
FU MONTH 24	Black	22	88,0	18	81,8	19,444	19,174	28	90,3	21	75,0	23,016	28,125
FU MONTH 36	Black	22	88,0	18	81,8	30,556	29,842	26	83,9	18	69,2	20,370	32,618
BASELINE	Asian	477	100,0	473	99,2	9,725	15,888	484	100,0	476	98,3	11,204	17,149
END OF ANTHRACYCLINE	Asian	370	77,6	356	96,2	6,554	13,208	375	77,5	366	97,6	8,834	16,348
WEEK 13	Asian	455	95,4	448	98,5	6,176	12,526	466	96,3	460	98,7	7,283	14,907
WEEK 25	Asian	450	94,3	444	98,7	7,207	13,964	465	96,1	454	97,6	8,003	14,509
END OF TREATMENT	Asian	475	99,6	448	94,3	7,961	14,141	484	100,0	459	94,8	9,441	15,860
FU MONTH 18	Asian	447	93,7	432	96,6	9,182	15,081	461	95,2	438	95,0	10,540	16,606
FU MONTH 24	Asian	442	92,7	419	94,8	9,268	14,661	445	91,9	416	93,5	11,378	16,729
FU MONTH 36	Asian	424	88,9	399	94,1	8,062	13,970	425	87,8	395	92,9	10,675	16,474
BASELINE	Other	52	100,0	49	94,2	17,687	23,176	51	100,0	45	88,2	18,889	19,003
END OF ANTHRACYCLINE	Other	38	73,1	36	94,7	13,426	20,244	36	70,6	33	91,7	13,131	17,057
WEEK 13	Other	49	94,2	45	91,8	13,704	21,108	45	88,2	43	95,6	18,992	23,169
WEEK 25	Other	49	94,2	46	93,9	15,217	22,174	42	82,4	39	92,9	12,821	17,296
END OF TREATMENT	Other	52	100,0	46	88,5	14,855	21,149	50	98,0	44	88,0	19,697	23,370
FU MONTH 18	Other	50	96,2	46	92,0	20,652	28,800	44	86,3	38	86,4	17,105	21,042
FU MONTH 24	Other	49	94,2	42	85,7	25,000	28,094	43	84,3	39	90,7	15,812	22,925
FU MONTH 36	Other	49	94,2	43	87,8	18,992	23,733	39	76,5	33	84,6	17,172	21,443
BASELINE	Missing	5	100,0	5	100,0	23,333	19,003	2	100,0	1	50,0	16,667	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	33,333	26,352	2	100,0	2	100,0	8,333	11,785
WEEK 13	Missing	5	100,0	5	100,0	20,000	21,731	2	100,0	2	100,0	16,667	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	36,667	13,944	2	100,0	2	100,0	16,667	23,570
END OF TREATMENT	Missing	5	100,0	4	80,0	41,667	9,623	2	100,0	1	50,0	16,667	NE
FU MONTH 18	Missing	5	100,0	5	100,0	46,667	13,944	2	100,0	2	100,0	16,667	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	45,833	15,957	2	100,0	2	100,0	33,333	47,140
FU MONTH 36	Missing	5	100,0	5	100,0	40,000	27,889	2	100,0	2	100,0	16,667	23,570

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC07_SG.xls
11AUG2020 15:58

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Enjoyment Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	712	39,3	52,154	30,596	1823	100,0	747	41,0	54,172	30,755
END OF ANTHRACYCLINE	n/a	1432	79,1	490	34,2	47,211	29,885	1446	79,3	550	38,0	44,788	30,113
WEEK 13	n/a	1688	93,2	549	32,5	38,798	27,730	1725	94,6	590	34,2	41,695	28,839
WEEK 25	n/a	1645	90,8	618	37,6	44,013	28,737	1688	92,6	662	39,2	47,331	28,501
END OF TREATMENT	n/a	1794	99,1	659	36,7	47,243	27,878	1811	99,3	733	40,5	47,794	28,096
FU MONTH 18	n/a	1663	91,8	675	40,6	50,469	27,972	1688	92,6	677	40,1	48,991	27,931
FU MONTH 24	n/a	1633	90,2	674	41,3	50,692	27,684	1638	89,9	680	41,5	49,461	27,845
FU MONTH 36	n/a	1571	86,7	629	40,0	50,185	28,255	1556	85,4	651	41,8	49,309	29,482
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	22	43,1	51,515	26,681	43	100,0	27	62,8	56,790	28,963
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	12	33,3	41,667	25,126	26	60,5	17	65,4	49,020	35,586
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	11	23,9	36,364	27,707	40	93,0	23	57,5	46,377	27,959
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	14	31,8	30,952	24,335	38	88,4	22	57,9	51,515	26,681
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	20	39,2	48,333	25,305	42	97,7	26	61,9	55,128	28,193
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	20	43,5	43,333	24,423	39	90,7	22	56,4	45,455	19,370

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	21	45,7	55,556	28,545	39	90,7	19	48,7	56,140	24,976
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	22	47,8	57,576	27,568	39	90,7	23	59,0	52,174	29,858
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	94	36,6	48,582	29,193	278	100,0	97	34,9	50,515	32,316
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	65	34,8	51,282	28,307	203	73,0	61	30,0	39,891	26,401
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	68	27,4	38,725	26,772	263	94,6	83	31,6	37,349	28,702
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	82	33,7	45,122	26,383	256	92,1	85	33,2	51,765	26,480
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	91	35,8	46,520	25,278	276	99,3	97	35,1	43,299	26,425
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	95	38,6	48,421	25,622	259	93,2	90	34,7	48,148	29,184
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	98	40,2	47,279	27,044	256	92,1	103	40,2	46,278	26,908
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	92	38,8	46,377	27,495	251	90,3	97	38,6	48,454	28,876
BASELINE	1-3 positive nodes	907	100,0	371	40,9	54,807	30,562	900	100,0	369	41,0	54,923	30,604
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	241	33,8	50,899	30,737	707	78,6	274	38,8	45,742	30,331
WEEK 13	1-3 positive nodes	847	93,4	298	35,2	40,380	26,639	854	94,9	278	32,6	42,686	28,048
WEEK 25	1-3 positive nodes	825	91,0	329	39,9	46,505	27,462	836	92,9	326	39,0	46,626	29,010
END OF TREATMENT	1-3 positive nodes	899	99,1	336	37,4	47,123	27,348	897	99,7	363	40,5	48,301	28,671
FU MONTH 18	1-3 positive nodes	838	92,4	351	41,9	52,991	27,425	852	94,7	345	40,5	49,469	28,197

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	350	42,3	53,333	26,705	830	92,2	357	43,0	49,300	28,437
FU MONTH 36	1-3 positive nodes	804	88,6	335	41,7	52,139	28,160	794	88,2	314	39,5	50,849	29,689
BASELINE	>= 4 positive nodes	596	100,0	225	37,8	49,333	31,352	602	100,0	254	42,2	54,199	30,619
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	172	34,7	40,891	28,631	510	84,7	198	38,8	44,613	30,444
WEEK 13	>= 4 positive nodes	547	91,8	172	31,4	36,240	29,911	568	94,4	206	36,3	41,586	30,029
WEEK 25	>= 4 positive nodes	533	89,4	193	36,2	40,242	31,523	558	92,7	229	41,0	46,288	28,648
END OF TREATMENT	>= 4 positive nodes	590	99,0	212	35,9	47,642	30,090	596	99,0	247	41,4	48,043	27,783
FU MONTH 18	>= 4 positive nodes	533	89,4	209	39,2	47,847	29,902	538	89,4	220	40,9	48,939	27,841
FU MONTH 24	>= 4 positive nodes	516	86,6	205	39,7	47,317	29,142	513	85,2	201	39,2	50,746	27,502
FU MONTH 36	>= 4 positive nodes	484	81,2	180	37,2	47,593	28,631	472	78,4	217	46,0	47,158	29,456
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	572	39,7	52,506	30,934	1448	100,0	593	41,0	54,132	30,730
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	489	34,2	47,171	29,903	1444	99,7	550	38,1	44,788	30,113
WEEK 13	Anthracycline containing regimen	1347	93,6	448	33,3	38,467	28,132	1374	94,9	478	34,8	41,283	28,505
WEEK 25	Anthracycline containing regimen	1311	91,1	512	39,1	45,182	28,945	1346	93,0	542	40,3	47,478	27,878

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	539	37,7	47,619	28,014	1444	99,7	589	40,8	47,199	28,208
FU MONTH 18	Anthracycline containing regimen	1329	92,4	539	40,6	50,402	28,622	1340	92,5	537	40,1	49,472	28,510
FU MONTH 24	Anthracycline containing regimen	1306	90,8	541	41,4	50,955	28,212	1308	90,3	551	42,1	49,002	27,753
FU MONTH 36	Anthracycline containing regimen	1259	87,5	510	40,5	50,261	28,553	1244	85,9	526	42,3	49,049	29,852
BASELINE	Non-anthracycline containing regimen	372	100,0	140	37,6	50,714	29,237	375	100,0	154	41,1	54,329	30,950
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	1	33,3	66,667	NE	2	0,5	0	0,0	NE	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	101	29,6	40,264	25,956	351	93,6	112	31,9	43,452	30,294
WEEK 25	Non-anthracycline containing regimen	334	89,8	106	31,7	38,365	27,136	342	91,2	120	35,1	46,667	31,281
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	120	32,9	45,556	27,308	367	97,9	144	39,2	50,231	27,594
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	136	40,7	50,735	25,326	348	92,8	140	40,2	47,143	25,598
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	133	40,7	49,624	25,497	330	88,0	129	39,1	51,421	28,262
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	119	38,1	49,860	27,057	312	83,2	125	40,1	50,400	27,958

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
Centrally assessed hormone receptor status													
BASELINE	Negative (ER and PgR negative)	864	100,0	315	36,5	49,947	29,668	858	100,0	332	38,7	51,506	31,110
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	204	30,4	45,915	29,587	661	77,0	231	34,9	43,001	29,616
WEEK 13	Negative (ER and PgR negative)	815	94,3	236	29,0	36,299	27,430	804	93,7	264	32,8	39,394	28,722
WEEK 25	Negative (ER and PgR negative)	799	92,5	268	33,5	43,657	28,508	786	91,6	286	36,4	46,270	28,057
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	296	34,6	45,608	26,952	854	99,5	323	37,8	45,098	27,911
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	294	36,7	49,320	27,220	781	91,0	304	38,9	46,491	27,660
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	298	37,9	48,434	27,343	763	88,9	299	39,2	47,826	27,679
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	290	38,5	48,621	28,143	735	85,7	298	40,5	47,427	29,380
BASELINE	Positive (ER and/or PgR positive)	947	100,0	397	41,9	53,904	31,239	965	100,0	415	43,0	56,305	30,336
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	286	37,6	48,135	30,114	785	81,3	319	40,6	46,082	30,449
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	313	35,9	40,682	27,850	921	95,4	326	35,4	43,558	28,842
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	350	41,4	44,286	28,948	902	93,5	376	41,7	48,138	28,846
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	363	38,7	48,577	28,578	957	99,2	410	42,8	49,919	28,092
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	381	44,2	51,356	28,543	907	94,0	373	41,1	51,028	28,022

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	376	44,4	52,482	27,858	875	90,7	381	43,5	50,744	27,944
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	339	41,4	51,524	28,324	821	85,1	353	43,0	50,897	29,516
Geographical region II													
BASELINE	USA/Canada	265	100,0	121	45,7	59,504	28,286	260	100,0	126	48,5	58,995	29,863
END OF ANTHRACYCLINE	USA/Canada	109	41,1	44	40,4	56,061	32,765	111	42,7	44	39,6	43,182	27,449
WEEK 13	USA/Canada	242	91,3	92	38,0	43,116	29,042	236	90,8	93	39,4	45,520	30,211
WEEK 25	USA/Canada	234	88,3	99	42,3	48,148	27,447	230	88,5	106	46,1	51,258	30,228
END OF TREATMENT	USA/Canada	259	97,7	108	41,7	50,000	27,907	255	98,1	122	47,8	52,186	28,098
FU MONTH 18	USA/Canada	238	89,8	106	44,5	55,031	26,041	231	88,8	101	43,7	54,125	27,019
FU MONTH 24	USA/Canada	231	87,2	113	48,9	53,392	26,926	224	86,2	96	42,9	55,903	29,218
FU MONTH 36	USA/Canada	223	84,2	97	43,5	53,952	27,404	205	78,8	94	45,9	52,837	28,674
BASELINE	Western Europe	827	100,0	353	42,7	59,207	29,048	822	100,0	373	45,4	61,305	29,952
END OF ANTHRACYCLINE	Western Europe	732	88,5	284	38,8	52,700	28,655	728	88,6	307	42,2	50,706	30,525
WEEK 13	Western Europe	764	92,4	271	35,5	44,157	27,173	778	94,6	294	37,8	46,599	29,689
WEEK 25	Western Europe	738	89,2	324	43,9	50,206	28,911	750	91,2	351	46,8	52,042	27,281
END OF TREATMENT	Western Europe	821	99,3	356	43,4	52,622	28,129	817	99,4	377	46,1	52,520	28,667
FU MONTH 18	Western Europe	754	91,2	359	47,6	54,689	28,442	764	92,9	351	45,9	54,701	29,101
FU MONTH 24	Western Europe	739	89,4	355	48,0	56,714	27,580	747	90,9	361	48,3	54,848	28,143
FU MONTH 36	Western Europe	713	86,2	345	48,4	55,266	28,168	712	86,6	328	46,1	55,691	29,055
BASELINE	Asia Pacific	490	100,0	150	30,6	32,444	25,601	512	100,0	159	31,1	40,881	27,024

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	79	20,7	29,536	24,453	397	77,5	114	28,7	36,550	27,683
WEEK 13	Asia Pacific	466	95,1	103	22,1	23,948	20,568	493	96,3	121	24,5	32,231	25,796
WEEK 25	Asia Pacific	461	94,1	110	23,9	28,182	23,106	492	96,1	130	26,4	34,103	26,726
END OF TREATMENT	Asia Pacific	487	99,4	112	23,0	30,655	20,572	512	100,0	153	29,9	35,730	22,975
FU MONTH 18	Asia Pacific	459	93,7	124	27,0	35,484	21,566	485	94,7	148	30,5	35,135	20,122
FU MONTH 24	Asia Pacific	454	92,7	122	26,9	33,880	20,545	470	91,8	154	32,8	33,550	19,618
FU MONTH 36	Asia Pacific	437	89,2	107	24,5	30,530	20,022	453	88,5	155	34,2	34,194	25,468
BASELINE	Latin America	43	100,0	13	30,2	53,846	32,026	47	100,0	20	42,6	45,000	22,361
END OF ANTHRACYCLINE	Latin America	29	67,4	9	31,0	29,630	38,889	32	68,1	9	28,1	25,926	27,778
WEEK 13	Latin America	40	93,0	12	30,0	30,556	30,011	44	93,6	16	36,4	33,333	21,082
WEEK 25	Latin America	39	90,7	16	41,0	22,917	26,440	44	93,6	15	34,1	37,778	30,516
END OF TREATMENT	Latin America	42	97,7	15	35,7	48,889	33,014	45	95,7	22	48,9	39,394	26,500
FU MONTH 18	Latin America	41	95,3	17	41,5	49,020	33,578	42	89,4	20	47,6	33,333	18,732
FU MONTH 24	Latin America	40	93,0	15	37,5	42,222	29,457	41	87,2	15	36,6	33,333	21,822
FU MONTH 36	Latin America	38	88,4	13	34,2	56,410	28,495	37	78,7	19	51,4	35,088	28,270
BASELINE	Other	186	100,0	75	40,3	46,222	32,370	182	100,0	69	37,9	40,097	32,125
END OF ANTHRACYCLINE	Other	181	97,3	74	40,9	41,892	28,166	178	97,8	76	42,7	36,404	28,377
WEEK 13	Other	176	94,6	71	40,3	35,681	28,908	174	95,6	66	37,9	33,838	23,745
WEEK 25	Other	173	93,0	69	39,9	39,130	26,170	172	94,5	60	34,9	43,889	26,391
END OF TREATMENT	Other	185	99,5	68	36,8	41,667	24,687	182	100,0	59	32,4	42,938	27,017
FU MONTH 18	Other	171	91,9	69	40,4	48,792	28,342	166	91,2	57	34,3	46,199	27,998
FU MONTH 24	Other	169	90,9	69	40,8	46,860	27,605	156	85,7	54	34,6	51,852	26,435

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Other	160	86,0	67	41,9	48,756	28,026	149	81,9	55	36,9	52,727	28,466
Protocol version													
BASELINE	Protocol A	1240	100,0	484	39,0	53,306	30,115	1246	100,0	528	42,4	55,366	30,949
END OF ANTHRACYCLINE	Protocol A	984	79,4	335	34,0	47,861	29,431	988	79,3	373	37,8	45,398	30,632
WEEK 13	Protocol A	1155	93,1	368	31,9	40,127	27,496	1180	94,7	399	33,8	42,272	29,716
WEEK 25	Protocol A	1125	90,7	419	37,2	44,630	29,160	1157	92,9	455	39,3	48,645	27,853
END OF TREATMENT	Protocol A	1229	99,1	454	36,9	47,137	28,022	1236	99,2	512	41,4	49,479	28,051
FU MONTH 18	Protocol A	1142	92,1	460	40,3	50,290	28,476	1156	92,8	476	41,2	50,140	29,059
FU MONTH 24	Protocol A	1124	90,6	468	41,6	50,926	27,963	1127	90,4	477	42,3	50,175	29,038
FU MONTH 36	Protocol A	1087	87,7	454	41,8	50,367	28,426	1069	85,8	455	42,6	50,110	29,837
BASELINE	Protocol Amendment B	571	100,0	228	39,9	49,708	31,521	577	100,0	219	38,0	51,294	30,156
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	155	34,6	45,806	30,895	458	79,4	177	38,6	43,503	29,034
WEEK 13	Protocol Amendment B	533	93,3	181	34,0	36,096	28,082	545	94,5	191	35,0	40,489	26,950
WEEK 25	Protocol Amendment B	520	91,1	199	38,3	42,714	27,853	531	92,0	207	39,0	44,444	29,742
END OF TREATMENT	Protocol Amendment B	565	98,9	205	36,3	47,480	27,622	575	99,7	221	38,4	43,891	27,873
FU MONTH 18	Protocol Amendment B	521	91,2	215	41,3	50,853	26,923	532	92,2	201	37,8	46,269	24,914
FU MONTH 24	Protocol Amendment B	509	89,1	206	40,5	50,162	27,100	511	88,6	203	39,7	47,783	24,804
FU MONTH 36	Protocol Amendment B	484	84,8	175	36,2	49,714	27,881	487	84,4	196	40,2	47,449	28,630
Nodal status													
BASELINE	0 positive nodes	308	100,0	116	37,7	49,138	28,644	321	100,0	124	38,6	51,882	31,609
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	77	34,5	49,784	27,901	229	71,3	78	34,1	41,880	28,647

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	0 positive nodes	294	95,5	79	26,9	38,397	26,735	303	94,4	106	35,0	39,308	28,655
WEEK 25	0 positive nodes	287	93,2	96	33,4	43,056	26,454	294	91,6	107	36,4	51,713	26,395
END OF TREATMENT	0 positive nodes	305	99,0	111	36,4	46,847	25,178	318	99,1	123	38,7	45,799	27,127
FU MONTH 18	0 positive nodes	292	94,8	115	39,4	47,536	25,386	298	92,8	112	37,6	47,619	27,478
FU MONTH 24	0 positive nodes	290	94,2	119	41,0	48,739	27,374	295	91,9	122	41,4	47,814	26,759
FU MONTH 36	0 positive nodes	283	91,9	114	40,3	48,538	27,744	290	90,3	120	41,4	49,167	28,976
BASELINE	>= 1 positive nodes	1503	100,0	596	39,7	52,740	30,950	1502	100,0	623	41,5	54,628	30,587
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	413	34,2	46,731	30,249	1217	81,0	472	38,8	45,268	30,351
WEEK 13	>= 1 positive nodes	1394	92,7	470	33,7	38,865	27,921	1422	94,7	484	34,0	42,218	28,882
WEEK 25	>= 1 positive nodes	1358	90,4	522	38,4	44,189	29,157	1394	92,8	555	39,8	46,486	28,836
END OF TREATMENT	>= 1 positive nodes	1489	99,1	548	36,8	47,324	28,414	1493	99,4	610	40,9	48,197	28,292
FU MONTH 18	>= 1 positive nodes	1371	91,2	560	40,8	51,071	28,457	1390	92,5	565	40,6	49,263	28,036
FU MONTH 24	>= 1 positive nodes	1343	89,4	555	41,3	51,111	27,757	1343	89,4	558	41,5	49,821	28,088
FU MONTH 36	>= 1 positive nodes	1288	85,7	515	40,0	50,550	28,381	1266	84,3	531	41,9	49,341	29,622
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	432	49,5	57,793	29,096	885	100,0	468	52,9	57,621	30,326
END OF ANTHRACYCLINE	Premenopausal	708	81,1	311	43,9	52,733	28,939	726	82,0	365	50,3	49,589	29,711

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Premenopausal	841	96,3	334	39,7	42,016	26,867	852	96,3	367	43,1	43,688	28,661
WEEK 25	Premenopausal	825	94,5	394	47,8	47,377	27,937	838	94,7	418	49,9	49,681	28,482
END OF TREATMENT	Premenopausal	866	99,2	411	47,5	51,257	28,235	881	99,5	463	52,6	50,108	27,382
FU MONTH 18	Premenopausal	819	93,8	423	51,6	55,477	26,973	835	94,4	419	50,2	53,222	27,709
FU MONTH 24	Premenopausal	803	92,0	431	53,7	54,911	27,581	807	91,2	425	52,7	52,706	27,158
FU MONTH 36	Premenopausal	765	87,6	393	51,4	54,283	27,652	773	87,3	406	52,5	53,859	28,977
BASELINE	Postmenopausal	933	100,0	277	29,7	43,321	30,832	929	100,0	275	29,6	48,242	30,671
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	177	24,6	37,288	28,923	711	76,5	183	25,7	34,973	28,448
WEEK 13	Postmenopausal	842	90,2	213	25,3	33,490	28,131	864	93,0	221	25,6	38,462	28,847
WEEK 25	Postmenopausal	815	87,4	221	27,1	37,557	28,820	841	90,5	243	28,9	43,210	28,156
END OF TREATMENT	Postmenopausal	923	98,9	246	26,7	40,379	25,821	921	99,1	269	29,2	43,742	28,923
FU MONTH 18	Postmenopausal	839	89,9	251	29,9	41,833	27,462	844	90,9	255	30,2	42,353	26,974
FU MONTH 24	Postmenopausal	825	88,4	240	29,1	42,778	25,940	823	88,6	254	30,9	44,226	28,107
FU MONTH 36	Postmenopausal	801	85,9	234	29,2	43,162	27,850	776	83,5	243	31,3	41,701	28,563
BASELINE	Unknown/Missing	5	100,0	3	60,0	55,556	38,490	9	100,0	4	44,4	58,333	31,914
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	2	40,0	66,667	47,140	9	100,0	2	22,2	66,667	47,140
WEEK 13	Unknown/Missing	5	100,0	2	40,0	66,667	47,140	9	100,0	2	22,2	33,333	47,140
WEEK 25	Unknown/Missing	5	100,0	3	60,0	77,778	38,490	9	100,0	1	11,1	66,667	NE
END OF TREATMENT	Unknown/Missing	5	100,0	2	40,0	66,667	47,140	9	100,0	1	11,1	66,667	NE
FU MONTH 18	Unknown/Missing	5	100,0	1	20,0	100,000	NE	9	100,0	3	33,3	22,222	19,245

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unknown/Missing	5	100,0	3	60,0	77,778	38,490	8	88,9	1	12,5	0,000	NE
FU MONTH 36	Unknown/Missing	5	100,0	2	40,0	66,667	47,140	7	77,8	2	28,6	50,000	70,711
Age II													
BASELINE	< 65	1581	100,0	661	41,8	53,555	30,255	1604	100,0	706	44,0	54,958	30,309
END OF ANTHRACYCLINE	< 65	1268	80,2	467	36,8	48,251	29,761	1287	80,2	522	40,6	45,849	30,014
WEEK 13	< 65	1497	94,7	516	34,5	39,470	27,460	1529	95,3	554	36,2	42,359	28,469
WEEK 25	< 65	1464	92,6	580	39,6	44,540	28,506	1501	93,6	626	41,7	47,977	28,416
END OF TREATMENT	< 65	1569	99,2	622	39,6	47,749	27,694	1596	99,5	690	43,2	48,357	27,904
FU MONTH 18	< 65	1474	93,2	629	42,7	51,457	27,455	1497	93,3	644	43,0	49,741	27,604
FU MONTH 24	< 65	1446	91,5	631	43,6	51,030	27,575	1450	90,4	649	44,8	49,923	27,724
FU MONTH 36	< 65	1390	87,9	587	42,2	50,880	28,164	1383	86,2	619	44,8	50,296	29,276
BASELINE	>= 65	230	100,0	51	22,2	33,987	29,432	219	100,0	41	18,7	40,650	35,365
END OF ANTHRACYCLINE	>= 65	164	71,3	23	14,0	26,087	24,529	159	72,6	28	17,6	25,000	25,051
WEEK 13	>= 65	191	83,0	33	17,3	28,283	30,186	196	89,5	36	18,4	31,481	32,800
WEEK 25	>= 65	181	78,7	38	21,0	35,965	31,367	187	85,4	36	19,3	36,111	28,031
END OF TREATMENT	>= 65	225	97,8	37	16,4	38,739	29,932	215	98,2	43	20,0	38,760	29,930
FU MONTH 18	>= 65	189	82,2	46	24,3	36,957	31,606	191	87,2	33	17,3	34,343	30,601
FU MONTH 24	>= 65	187	81,3	43	23,0	45,736	29,117	188	85,8	31	16,5	39,785	29,084
FU MONTH 36	>= 65	181	78,7	42	23,2	40,476	28,069	173	79,0	32	18,5	30,208	27,251
Histological grade													
BASELINE	Grade 1	32	100,0	15	46,9	60,000	18,687	24	100,0	11	45,8	51,515	31,140
END OF ANTHRACYCLINE	Grade 1	18	56,3	7	38,9	47,619	17,817	17	70,8	7	41,2	47,619	32,530
WEEK 13	Grade 1	31	96,9	10	32,3	40,000	21,082	23	95,8	6	26,1	38,889	38,968
WEEK 25	Grade 1	31	96,9	12	38,7	36,111	22,285	23	95,8	6	26,1	61,111	25,092

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Grade 1	31	96,9	14	45,2	50,000	25,318	24	100,0	9	37,5	40,741	32,394
FU MONTH 18	Grade 1	30	93,8	15	50,0	60,000	22,537	23	95,8	10	43,5	46,667	28,109
FU MONTH 24	Grade 1	28	87,5	13	46,4	56,410	25,036	23	95,8	9	39,1	48,148	29,397
FU MONTH 36	Grade 1	27	84,4	11	40,7	54,545	26,968	22	91,7	7	31,8	38,095	23,002
BASELINE	Grade 2	552	100,0	215	38,9	47,752	32,447	557	100,0	235	42,2	50,638	31,777
END OF ANTHRACYCLINE	Grade 2	445	80,6	166	37,3	46,185	32,132	446	80,1	181	40,6	42,726	30,493
WEEK 13	Grade 2	507	91,8	181	35,7	36,648	29,419	524	94,1	183	34,9	39,891	28,912
WEEK 25	Grade 2	494	89,5	190	38,5	43,509	30,506	515	92,5	215	41,7	44,031	29,609
END OF TREATMENT	Grade 2	548	99,3	208	38,0	47,596	29,753	553	99,3	231	41,8	45,743	29,157
FU MONTH 18	Grade 2	507	91,8	203	40,0	50,411	28,601	517	92,8	200	38,7	47,333	27,222
FU MONTH 24	Grade 2	501	90,8	201	40,1	51,244	29,247	500	89,8	206	41,2	50,162	28,274
FU MONTH 36	Grade 2	487	88,2	191	39,2	51,483	30,336	476	85,5	205	43,1	47,967	29,381
BASELINE	Grade 3	1161	100,0	464	40,0	53,807	29,796	1173	100,0	483	41,2	56,039	29,941
END OF ANTHRACYCLINE	Grade 3	918	79,1	309	33,7	47,573	28,781	919	78,3	348	37,9	45,594	29,778
WEEK 13	Grade 3	1088	93,7	341	31,3	40,176	27,154	1114	95,0	387	34,7	42,550	28,663
WEEK 25	Grade 3	1059	91,2	400	37,8	44,583	28,094	1087	92,7	424	39,0	48,821	27,479
END OF TREATMENT	Grade 3	1150	99,1	418	36,3	47,289	27,204	1165	99,3	477	40,9	48,567	27,346
FU MONTH 18	Grade 3	1067	91,9	439	41,1	50,494	27,846	1085	92,5	450	41,5	49,556	28,159
FU MONTH 24	Grade 3	1046	90,1	442	42,3	50,679	27,324	1053	89,8	448	42,5	49,330	27,571
FU MONTH 36	Grade 3	1002	86,3	413	41,2	49,718	27,441	999	85,2	424	42,4	50,550	29,615
BASELINE	Unevaluable/Unknown/Missing	66	100,0	18	27,3	55,556	32,338	69	100,0	18	26,1	51,852	36,555

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	8	15,7	54,167	35,355	64	92,8	14	21,9	50,000	33,968
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	17	27,4	33,333	23,570	64	92,8	14	21,9	42,857	30,462
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	16	26,2	41,667	28,545	63	91,3	17	27,0	47,059	37,377
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	19	29,2	40,351	23,776	69	100,0	16	23,2	58,333	31,032
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	18	30,5	42,593	27,548	63	91,3	17	27,0	54,902	31,049
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	18	31,0	40,741	18,277	62	89,9	17	27,4	45,098	31,049
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	14	25,5	42,857	24,209	59	85,5	15	25,4	37,778	27,794
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	287	39,4	58,537	28,761	715	100,0	299	41,8	55,853	30,133
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	206	34,8	53,074	28,867	572	80,0	231	40,4	46,176	30,353
WEEK 13	Breast conserving surgery	677	93,0	212	31,3	43,396	26,631	673	94,1	241	35,8	42,047	28,910
WEEK 25	Breast conserving surgery	665	91,3	237	35,6	46,132	27,622	654	91,5	277	42,4	48,977	28,303
END OF TREATMENT	Breast conserving surgery	722	99,2	273	37,8	49,695	26,370	711	99,4	296	41,6	51,914	28,326
FU MONTH 18	Breast conserving surgery	678	93,1	287	42,3	52,962	27,132	659	92,2	275	41,7	51,758	27,756
FU MONTH 24	Breast conserving surgery	666	91,5	290	43,5	53,563	27,112	644	90,1	292	45,3	51,826	28,859

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Breast conserving surgery	651	89,4	269	41,3	53,903	27,436	616	86,2	274	44,5	51,946	28,925
BASELINE	Mastectomy	1083	100,0	425	39,2	47,843	31,074	1107	100,0	448	40,5	53,051	31,145
END OF ANTHRACYCLINE	Mastectomy	840	77,6	284	33,8	42,958	29,941	873	78,9	319	36,5	43,783	29,946
WEEK 13	Mastectomy	1011	93,4	337	33,3	35,905	28,054	1051	94,9	349	33,2	41,452	28,829
WEEK 25	Mastectomy	980	90,5	381	38,9	42,695	29,367	1033	93,3	385	37,3	46,147	28,621
END OF TREATMENT	Mastectomy	1072	99,0	386	36,0	45,509	28,805	1099	99,3	437	39,8	45,004	27,624
FU MONTH 18	Mastectomy	985	91,0	388	39,4	48,625	28,471	1028	92,9	402	39,1	47,098	27,926
FU MONTH 24	Mastectomy	967	89,3	384	39,7	48,524	27,948	993	89,7	388	39,1	47,680	26,958
FU MONTH 36	Mastectomy	920	84,9	360	39,1	47,407	28,575	939	84,8	377	40,1	47,392	29,772
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	275	41,7	52,485	29,951	665	100,0	287	43,2	54,355	31,342
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	183	35,3	47,905	28,923	523	78,6	208	39,8	42,788	29,694
WEEK 13	0 - < 2 cm	620	93,9	206	33,2	41,748	28,215	631	94,9	232	36,8	40,517	30,009
WEEK 25	0 - < 2 cm	608	92,1	239	39,3	46,304	29,214	617	92,8	261	42,3	48,148	29,268
END OF TREATMENT	0 - < 2 cm	655	99,2	258	39,4	48,837	27,125	661	99,4	274	41,5	49,878	29,270

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	0 - < 2 cm	617	93,5	257	41,7	54,475	26,485	624	93,8	278	44,6	50,240	27,859
FU MONTH 24	0 - < 2 cm	607	92,0	261	43,0	54,023	27,999	606	91,1	268	44,2	50,746	28,035
FU MONTH 36	0 - < 2 cm	596	90,3	254	42,6	53,018	27,438	580	87,2	252	43,4	50,926	29,815
BASELINE	>= 2 - < 5 cm	1009	100,0	382	37,9	52,705	30,115	991	100,0	400	40,4	53,833	31,072
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	264	33,1	47,601	30,113	789	79,6	292	37,0	45,205	30,832
WEEK 13	>= 2 - < 5 cm	935	92,7	292	31,2	37,785	27,061	940	94,9	305	32,4	41,858	28,231
WEEK 25	>= 2 - < 5 cm	910	90,2	326	35,8	42,331	27,688	919	92,7	341	37,1	46,823	28,247
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	344	34,5	46,221	27,858	985	99,4	388	39,4	46,392	27,135
FU MONTH 18	>= 2 - < 5 cm	923	91,5	367	39,8	48,683	28,692	914	92,2	339	37,1	48,279	27,844
FU MONTH 24	>= 2 - < 5 cm	905	89,7	362	40,0	48,435	27,275	889	89,7	360	40,5	48,426	27,772
FU MONTH 36	>= 2 - < 5 cm	857	84,9	330	38,5	48,081	28,435	839	84,7	343	40,9	48,688	29,684
BASELINE	>= 5 cm	139	100,0	54	38,8	46,914	36,925	165	100,0	59	35,8	55,932	25,850
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	41	36,3	42,276	33,354	132	80,0	48	36,4	50,694	27,496
WEEK 13	>= 5 cm	130	93,5	49	37,7	32,653	29,258	152	92,1	51	33,6	45,752	27,456
WEEK 25	>= 5 cm	124	89,2	51	41,1	44,444	33,110	150	90,9	59	39,3	46,893	27,065
END OF TREATMENT	>= 5 cm	138	99,3	55	39,9	46,667	31,164	163	98,8	70	42,9	47,619	28,698
FU MONTH 18	>= 5 cm	120	86,3	49	40,8	44,218	27,544	148	89,7	59	39,9	47,458	29,167
FU MONTH 24	>= 5 cm	118	84,9	50	42,4	49,333	27,962	141	85,5	51	36,2	50,327	27,787
FU MONTH 36	>= 5 cm	115	82,7	44	38,3	50,000	30,920	135	81,8	55	40,7	46,061	26,829
BASELINE	Missing	3	100,0	1	33,3	33,333	NE	2	100,0	1	50,0	33,333	NE
END OF ANTHRACYCLINE	Missing	3	100,0	2	66,7	33,333	0,000	2	100,0	2	100,0	50,000	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Missing	3	100,0	2	66,7	33,333	0,000	2	100,0	2	100,0	50,000	23,570
WEEK 25	Missing	3	100,0	2	66,7	33,333	0,000	2	100,0	1	50,0	33,333	NE
END OF TREATMENT	Missing	3	100,0	2	66,7	33,333	47,140	2	100,0	1	50,0	33,333	NE
FU MONTH 18	Missing	3	100,0	2	66,7	16,667	23,570	2	100,0	1	50,0	33,333	NE
FU MONTH 24	Missing	3	100,0	1	33,3	66,667	NE	2	100,0	1	50,0	33,333	NE
FU MONTH 36	Missing	3	100,0	1	33,3	33,333	NE	2	100,0	1	50,0	33,333	NE
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	559	41,5	54,502	30,708	1350	100,0	567	42,0	55,673	30,224
END OF ANTHRACYCLINE	Yes	1103	81,9	407	36,9	48,239	29,622	1104	81,8	435	39,4	45,517	30,480
WEEK 13	Yes	1308	97,1	440	33,6	39,697	27,828	1324	98,1	466	35,2	41,845	28,696
WEEK 25	Yes	1277	94,8	490	38,4	44,354	29,246	1302	96,4	531	40,8	47,520	28,660
END OF TREATMENT	Yes	1347	100,0	537	39,9	47,983	28,224	1350	100,0	579	42,9	49,165	28,292
FU MONTH 18	Yes	1291	95,8	546	42,3	51,038	27,833	1298	96,1	541	41,7	50,647	28,220
FU MONTH 24	Yes	1266	94,0	542	42,8	51,538	28,023	1260	93,3	540	42,9	51,173	28,293
FU MONTH 36	Yes	1219	90,5	488	40,0	51,844	28,036	1195	88,5	514	43,0	51,427	29,270
BASELINE	No	464	100,0	153	33,0	43,573	28,685	473	100,0	180	38,1	49,444	31,998
END OF ANTHRACYCLINE	No	329	70,9	83	25,2	42,169	30,835	342	72,3	115	33,6	42,029	28,643
WEEK 13	No	380	81,9	109	28,7	35,168	27,154	401	84,8	124	30,9	41,129	29,482
WEEK 25	No	368	79,3	128	34,8	42,708	26,764	386	81,6	131	33,9	46,565	27,944
END OF TREATMENT	No	447	96,3	122	27,3	43,989	26,161	461	97,5	154	33,4	42,641	26,812
FU MONTH 18	No	372	80,2	129	34,7	48,062	28,537	390	82,5	136	34,9	42,402	25,809
FU MONTH 24	No	367	79,1	132	36,0	47,222	26,062	378	79,9	140	37,0	42,857	25,061
FU MONTH 36	No	352	75,9	141	40,1	44,444	28,359	361	76,3	137	38,0	41,363	29,016
Race													
BASELINE	White	1252	100,0	541	43,2	57,733	29,262	1255	100,0	574	45,7	59,001	30,561

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	White	1010	80,7	399	39,5	51,378	28,798	1018	81,1	430	42,2	48,062	30,791
WEEK 13	White	1158	92,5	429	37,0	41,958	27,640	1183	94,3	454	38,4	44,714	29,387
WEEK 25	White	1120	89,5	485	43,3	48,385	28,350	1150	91,6	523	45,5	51,562	28,049
END OF TREATMENT	White	1238	98,9	523	42,2	50,542	27,705	1244	99,1	561	45,1	51,812	28,333
FU MONTH 18	White	1138	90,9	528	46,4	53,725	28,208	1152	91,8	522	45,3	53,384	28,435
FU MONTH 24	White	1115	89,1	529	47,4	54,379	27,719	1120	89,2	515	46,0	54,951	27,950
FU MONTH 36	White	1071	85,5	503	47,0	54,009	28,010	1064	84,8	492	46,2	55,081	28,762
BASELINE	Black	25	100,0	10	40,0	43,333	38,650	31	100,0	11	35,5	51,515	37,605
END OF ANTHRACYCLINE	Black	9	36,0	4	44,4	50,000	33,333	15	48,4	8	53,3	41,667	23,570
WEEK 13	Black	21	84,0	6	28,6	55,556	27,217	29	93,5	10	34,5	40,000	26,294
WEEK 25	Black	21	84,0	7	33,3	61,905	23,002	29	93,5	11	37,9	42,424	33,635
END OF TREATMENT	Black	24	96,0	10	41,7	43,333	31,623	31	100,0	14	45,2	47,619	36,314
FU MONTH 18	Black	23	92,0	7	30,4	61,905	23,002	29	93,5	11	37,9	42,424	30,151
FU MONTH 24	Black	22	88,0	10	45,5	53,333	23,307	28	90,3	9	32,1	48,148	29,397
FU MONTH 36	Black	22	88,0	10	45,5	46,667	28,109	26	83,9	7	26,9	47,619	32,530
BASELINE	Asian	477	100,0	143	30,0	30,769	24,411	484	100,0	141	29,1	36,170	23,734
END OF ANTHRACYCLINE	Asian	370	77,6	72	19,5	23,611	20,508	375	77,5	100	26,7	32,000	23,172
WEEK 13	Asian	455	95,4	99	21,8	23,569	21,953	466	96,3	106	22,7	28,931	24,806
WEEK 25	Asian	450	94,3	106	23,6	25,472	20,856	465	96,1	113	24,3	29,499	22,604
END OF TREATMENT	Asian	475	99,6	107	22,5	29,907	19,390	484	100,0	135	27,9	31,605	20,082
FU MONTH 18	Asian	447	93,7	118	26,4	33,333	18,997	461	95,2	125	27,1	32,533	18,677
FU MONTH 24	Asian	442	92,7	111	25,1	32,132	19,031	445	91,9	139	31,2	30,216	16,493
FU MONTH 36	Asian	424	88,9	97	22,9	29,210	18,793	425	87,8	133	31,3	29,323	22,110

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Other	52	100,0	16	30,8	56,250	35,940	51	100,0	21	41,2	44,444	28,545
END OF ANTHRACYCLINE	Other	38	73,1	12	31,6	41,667	42,935	36	70,6	12	33,3	36,111	33,207
WEEK 13	Other	49	94,2	14	28,6	40,476	32,499	45	88,2	19	42,2	42,105	18,732
WEEK 25	Other	49	94,2	17	34,7	25,490	27,712	42	82,4	15	35,7	37,778	27,794
END OF TREATMENT	Other	52	100,0	16	30,8	52,083	34,359	50	98,0	23	46,0	44,928	23,802
FU MONTH 18	Other	50	96,2	18	36,0	59,259	29,273	44	86,3	19	43,2	40,351	21,020
FU MONTH 24	Other	49	94,2	20	40,8	51,667	27,519	43	84,3	16	37,2	41,667	28,545
FU MONTH 36	Other	49	94,2	16	32,7	54,167	26,874	39	76,5	18	46,2	38,889	30,785
BASELINE	Missing	5	100,0	2	40,0	83,333	23,570	2	100,0	0	0,0	NE	NE
END OF ANTHRACYCLINE	Missing	5	100,0	3	60,0	77,778	38,490	2	100,0	0	0,0	NE	NE
WEEK 13	Missing	5	100,0	1	20,0	66,667	NE	2	100,0	1	50,0	33,333	NE
WEEK 25	Missing	5	100,0	3	60,0	55,556	50,918	2	100,0	0	0,0	NE	NE
END OF TREATMENT	Missing	5	100,0	3	60,0	77,778	38,490	2	100,0	0	0,0	NE	NE
FU MONTH 18	Missing	5	100,0	4	80,0	66,667	38,490	2	100,0	0	0,0	NE	NE
FU MONTH 24	Missing	5	100,0	4	80,0	66,667	38,490	2	100,0	1	50,0	33,333	NE
FU MONTH 36	Missing	5	100,0	3	60,0	77,778	38,490	2	100,0	1	50,0	66,667	NE

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC08_SG.xls
11AUG2020 16:00

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Future Perspective Item
MODEL: --
STUDY: BO25126
Compliance/mean

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
BASELINE	n/a	1811	100,0	1746	96,4	51,203	31,741	1823	100,0	1761	96,6	50,445	31,821
END OF ANTHRACYCLINE	n/a	1432	79,1	1337	93,4	51,733	31,836	1446	79,3	1357	93,8	50,651	31,679
WEEK 13	n/a	1688	93,2	1599	94,7	53,763	31,126	1725	94,6	1634	94,7	52,020	31,001
WEEK 25	n/a	1645	90,8	1580	96,0	57,046	30,894	1688	92,6	1596	94,5	56,057	30,212
END OF TREATMENT	n/a	1794	99,1	1565	87,2	59,979	29,883	1811	99,3	1621	89,5	57,495	30,534
FU MONTH 18	n/a	1663	91,8	1475	88,7	63,887	29,118	1688	92,6	1461	86,6	60,233	29,423
FU MONTH 24	n/a	1633	90,2	1416	86,7	65,184	28,580	1638	89,9	1418	86,6	62,694	29,274
FU MONTH 36	n/a	1571	86,7	1380	87,8	66,111	28,817	1556	85,4	1342	86,2	63,934	30,176
Nodal status and tumor size													
BASELINE	0 positive nodes and tumor <= 1cm	51	100,0	49	96,1	59,184	34,871	43	100,0	40	93,0	60,000	30,382
END OF ANTHRACYCLINE	0 positive nodes and tumor <= 1cm	36	70,6	31	86,1	46,237	30,644	26	60,5	25	96,2	46,667	34,694
WEEK 13	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	51,938	32,775	40	93,0	39	97,5	52,137	34,872
WEEK 25	0 positive nodes and tumor <= 1cm	44	86,3	43	97,7	56,589	35,288	38	88,4	35	92,1	58,095	31,667
END OF TREATMENT	0 positive nodes and tumor <= 1cm	51	100,0	43	84,3	58,140	28,259	42	97,7	37	88,1	58,559	32,778
FU MONTH 18	0 positive nodes and tumor <= 1cm	46	90,2	43	93,5	63,566	23,920	39	90,7	35	89,7	58,095	30,618

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes and tumor <= 1cm	46	90,2	42	91,3	68,254	25,452	39	90,7	34	87,2	63,725	26,423
FU MONTH 36	0 positive nodes and tumor <= 1cm	46	90,2	44	95,7	65,909	30,911	39	90,7	37	94,9	65,766	27,763
BASELINE	0 positive nodes and tumor > 1cm	257	100,0	248	96,5	50,941	31,445	278	100,0	269	96,8	53,284	31,322
END OF ANTHRACYCLINE	0 positive nodes and tumor > 1cm	187	72,8	177	94,7	54,991	30,596	203	73,0	191	94,1	52,356	32,336
WEEK 13	0 positive nodes and tumor > 1cm	248	96,5	233	94,0	57,082	30,773	263	94,6	253	96,2	53,228	31,628
WEEK 25	0 positive nodes and tumor > 1cm	243	94,6	238	97,9	58,263	31,887	256	92,1	247	96,5	55,735	29,482
END OF TREATMENT	0 positive nodes and tumor > 1cm	254	98,8	225	88,6	62,963	28,887	276	99,3	254	92,0	60,367	29,706
FU MONTH 18	0 positive nodes and tumor > 1cm	246	95,7	218	88,6	66,208	29,238	259	93,2	228	88,0	63,158	26,867
FU MONTH 24	0 positive nodes and tumor > 1cm	244	94,9	207	84,8	69,082	28,813	256	92,1	228	89,1	66,520	27,186
FU MONTH 36	0 positive nodes and tumor > 1cm	237	92,2	212	89,5	67,767	27,989	251	90,3	225	89,6	63,111	30,165
BASELINE	1-3 positive nodes	907	100,0	880	97,0	51,818	31,588	900	100,0	867	96,3	51,442	31,495
END OF ANTHRACYCLINE	1-3 positive nodes	713	78,6	659	92,4	51,998	31,946	707	78,6	664	93,9	50,552	31,599
WEEK 13	1-3 positive nodes	847	93,4	800	94,5	53,333	31,422	854	94,9	803	94,0	52,968	30,018
WEEK 25	1-3 positive nodes	825	91,0	782	94,8	57,374	30,345	836	92,9	786	94,0	57,634	30,362
END OF TREATMENT	1-3 positive nodes	899	99,1	778	86,5	59,469	30,056	897	99,7	807	90,0	57,580	30,301
FU MONTH 18	1-3 positive nodes	838	92,4	732	87,4	64,071	28,664	852	94,7	740	86,9	60,991	29,289

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	1-3 positive nodes	827	91,2	718	86,8	63,649	29,065	830	92,2	722	87,0	63,804	28,812
FU MONTH 36	1-3 positive nodes	804	88,6	698	86,8	65,855	29,138	794	88,2	661	83,2	65,154	29,662
BASELINE	>= 4 positive nodes	596	100,0	569	95,5	49,678	31,777	602	100,0	585	97,2	47,009	32,335
END OF ANTHRACYCLINE	>= 4 positive nodes	496	83,2	470	94,8	50,496	32,191	510	84,7	477	93,5	50,314	31,431
WEEK 13	>= 4 positive nodes	547	91,8	523	95,6	53,091	30,682	568	94,4	539	94,9	50,031	31,836
WEEK 25	>= 4 positive nodes	533	89,4	517	97,0	56,028	30,932	558	92,7	528	94,6	53,725	30,159
END OF TREATMENT	>= 4 positive nodes	590	99,0	519	88,0	59,602	30,182	596	99,0	523	87,8	55,895	31,100
FU MONTH 18	>= 4 positive nodes	533	89,4	482	90,4	62,586	30,160	538	89,4	458	85,1	57,715	30,633
FU MONTH 24	>= 4 positive nodes	516	86,6	449	87,0	65,553	27,840	513	85,2	434	84,6	58,756	30,919
FU MONTH 36	>= 4 positive nodes	484	81,2	426	88,0	65,728	28,545	472	78,4	419	88,8	62,291	31,182
Adjuvant chemotherapy regimen													
BASELINE	Anthracycline containing regimen	1439	100,0	1390	96,6	50,240	32,241	1448	100,0	1400	96,7	49,762	31,958
END OF ANTHRACYCLINE	Anthracycline containing regimen	1429	99,3	1335	93,4	51,710	31,828	1444	99,7	1356	93,9	50,639	31,688
WEEK 13	Anthracycline containing regimen	1347	93,6	1284	95,3	53,505	31,127	1374	94,9	1300	94,6	52,359	30,903
WEEK 25	Anthracycline containing regimen	1311	91,1	1254	95,7	57,044	31,054	1346	93,0	1272	94,5	56,394	30,458
END OF TREATMENT	Anthracycline containing regimen	1429	99,3	1251	87,5	59,606	30,183	1444	99,7	1298	89,9	57,114	30,661

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	Anthracycline containing regimen	1329	92,4	1176	88,5	63,577	29,252	1340	92,5	1169	87,2	59,994	29,858
FU MONTH 24	Anthracycline containing regimen	1306	90,8	1133	86,8	64,990	28,579	1308	90,3	1131	86,5	62,334	30,010
FU MONTH 36	Anthracycline containing regimen	1259	87,5	1101	87,5	65,940	28,841	1244	85,9	1077	86,6	64,253	30,219
BASELINE	Non-anthracycline containing regimen	372	100,0	356	95,7	54,963	29,450	375	100,0	361	96,3	53,093	31,187
END OF ANTHRACYCLINE	Non-anthracycline containing regimen	3	0,8	2	66,7	66,667	47,140	2	0,5	1	50,0	66,667	NE
WEEK 13	Non-anthracycline containing regimen	341	91,7	315	92,4	54,815	31,148	351	93,6	334	95,2	50,699	31,393
WEEK 25	Non-anthracycline containing regimen	334	89,8	326	97,6	57,055	30,320	342	91,2	324	94,7	54,733	29,236
END OF TREATMENT	Non-anthracycline containing regimen	365	98,1	314	86,0	61,465	28,658	367	97,9	323	88,0	59,030	30,013
FU MONTH 18	Non-anthracycline containing regimen	334	89,8	299	89,5	65,106	28,598	348	92,8	292	83,9	61,187	27,642
FU MONTH 24	Non-anthracycline containing regimen	327	87,9	283	86,5	65,960	28,619	330	88,0	287	87,0	64,111	26,172
FU MONTH 36	Non-anthracycline containing regimen	312	83,9	279	89,4	66,786	28,763	312	83,2	265	84,9	62,642	30,021
Centrally assessed hormone receptor status													

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
BASELINE	Negative (ER and PgR negative)	864	100,0	835	96,6	51,737	32,370	858	100,0	830	96,7	51,124	32,137
END OF ANTHRACYCLINE	Negative (ER and PgR negative)	672	77,8	635	94,5	52,651	31,792	661	77,0	622	94,1	50,161	33,131
WEEK 13	Negative (ER and PgR negative)	815	94,3	772	94,7	55,440	31,222	804	93,7	772	96,0	52,116	31,577
WEEK 25	Negative (ER and PgR negative)	799	92,5	774	96,9	58,140	31,203	786	91,6	748	95,2	56,283	29,484
END OF TREATMENT	Negative (ER and PgR negative)	856	99,1	761	88,9	60,096	29,529	854	99,5	761	89,1	58,388	30,446
FU MONTH 18	Negative (ER and PgR negative)	801	92,7	715	89,3	64,942	29,602	781	91,0	689	88,2	60,087	29,178
FU MONTH 24	Negative (ER and PgR negative)	787	91,1	690	87,7	67,150	28,335	763	88,9	672	88,1	63,145	28,644
FU MONTH 36	Negative (ER and PgR negative)	753	87,2	672	89,2	66,766	28,716	735	85,7	652	88,7	62,628	31,120
BASELINE	Positive (ER and/or PgR positive)	947	100,0	911	96,2	50,714	31,163	965	100,0	931	96,5	49,839	31,542
END OF ANTHRACYCLINE	Positive (ER and/or PgR positive)	760	80,3	702	92,4	50,902	31,875	785	81,3	735	93,6	51,066	30,412
WEEK 13	Positive (ER and/or PgR positive)	873	92,2	827	94,7	52,197	30,973	921	95,4	862	93,6	51,933	30,495
WEEK 25	Positive (ER and/or PgR positive)	846	89,3	806	95,3	55,997	30,578	902	93,5	848	94,0	55,857	30,857
END OF TREATMENT	Positive (ER and/or PgR positive)	938	99,0	804	85,7	59,867	30,232	957	99,2	860	89,9	56,705	30,606
FU MONTH 18	Positive (ER and/or PgR positive)	862	91,0	760	88,2	62,895	28,639	907	94,0	772	85,1	60,363	29,659
FU MONTH 24	Positive (ER and/or PgR positive)	846	89,3	726	85,8	63,315	28,705	875	90,7	746	85,3	62,288	29,842

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Positive (ER and/or PgR positive)	818	86,4	708	86,6	65,490	28,918	821	85,1	690	84,0	65,169	29,224
Geographical region II													
BASELINE	USA/Canada	265	100,0	258	97,4	56,331	28,901	260	100,0	249	95,8	52,477	31,600
END OF ANTHRACYCLINE	USA/Canada	109	41,1	101	92,7	57,096	27,218	111	42,7	105	94,6	51,746	29,592
WEEK 13	USA/Canada	242	91,3	229	94,6	55,459	28,366	236	90,8	224	94,9	49,405	30,762
WEEK 25	USA/Canada	234	88,3	225	96,2	55,852	28,980	230	88,5	217	94,3	54,839	29,193
END OF TREATMENT	USA/Canada	259	97,7	216	83,4	60,185	28,920	255	98,1	228	89,4	58,772	31,226
FU MONTH 18	USA/Canada	238	89,8	194	81,5	63,230	29,380	231	88,8	178	77,1	62,172	27,986
FU MONTH 24	USA/Canada	231	87,2	186	80,5	62,724	30,155	224	86,2	176	78,6	62,879	27,571
FU MONTH 36	USA/Canada	223	84,2	179	80,3	66,853	30,085	205	78,8	154	75,1	64,069	29,651
BASELINE	Western Europe	827	100,0	778	94,1	47,601	32,320	822	100,0	778	94,6	47,986	31,856
END OF ANTHRACYCLINE	Western Europe	732	88,5	662	90,4	50,000	32,322	728	88,6	658	90,4	49,341	31,967
WEEK 13	Western Europe	764	92,4	693	90,7	52,814	31,964	778	94,6	705	90,6	51,300	31,311
WEEK 25	Western Europe	738	89,2	688	93,2	56,347	31,386	750	91,2	678	90,4	55,752	30,941
END OF TREATMENT	Western Europe	821	99,3	685	83,4	58,102	31,344	817	99,4	699	85,6	55,556	31,500
FU MONTH 18	Western Europe	754	91,2	641	85,0	63,599	29,568	764	92,9	619	81,0	59,343	30,639
FU MONTH 24	Western Europe	739	89,4	599	81,1	65,832	28,548	747	90,9	615	82,3	61,626	31,055
FU MONTH 36	Western Europe	713	86,2	605	84,9	66,171	29,054	712	86,6	590	82,9	63,164	30,757
BASELINE	Asia Pacific	490	100,0	485	99,0	57,113	29,658	512	100,0	507	99,0	58,580	29,308
END OF ANTHRACYCLINE	Asia Pacific	381	77,8	373	97,9	55,675	31,511	397	77,5	390	98,2	57,009	30,245
WEEK 13	Asia Pacific	466	95,1	464	99,6	56,968	29,706	493	96,3	492	99,8	57,791	28,388
WEEK 25	Asia Pacific	461	94,1	461	100,0	59,725	30,456	492	96,1	488	99,2	60,451	28,179

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Asia Pacific	487	99,4	464	95,3	64,296	27,216	512	100,0	490	95,7	63,605	27,001
FU MONTH 18	Asia Pacific	459	93,7	450	98,0	66,370	26,879	485	94,7	473	97,5	63,707	26,587
FU MONTH 24	Asia Pacific	454	92,7	441	97,1	67,423	26,675	470	91,8	446	94,9	66,816	25,674
FU MONTH 36	Asia Pacific	437	89,2	417	95,4	67,626	27,428	453	88,5	432	95,4	67,207	27,572
BASELINE	Latin America	43	100,0	42	97,7	61,111	32,020	47	100,0	46	97,9	46,377	33,317
END OF ANTHRACYCLINE	Latin America	29	67,4	29	100,0	65,517	27,434	32	68,1	32	100,0	50,000	33,867
WEEK 13	Latin America	40	93,0	40	100,0	68,333	32,860	44	93,6	44	100,0	49,242	35,575
WEEK 25	Latin America	39	90,7	39	100,0	70,085	27,354	44	93,6	44	100,0	50,758	30,063
END OF TREATMENT	Latin America	42	97,7	38	90,5	71,053	24,716	45	95,7	42	93,3	55,556	31,808
FU MONTH 18	Latin America	41	95,3	37	90,2	73,874	27,369	42	89,4	40	95,2	59,167	31,566
FU MONTH 24	Latin America	40	93,0	36	90,0	75,000	25,666	41	87,2	39	95,1	60,684	29,491
FU MONTH 36	Latin America	38	88,4	34	89,5	69,608	26,423	37	78,7	36	97,3	62,963	30,631
BASELINE	Other	186	100,0	183	98,4	41,348	33,826	182	100,0	181	99,5	36,464	32,146
END OF ANTHRACYCLINE	Other	181	97,3	172	95,0	44,380	31,849	178	97,8	172	96,6	40,698	31,797
WEEK 13	Other	176	94,6	173	98,3	43,353	31,783	174	95,6	169	97,1	42,406	33,082
WEEK 25	Other	173	93,0	167	96,5	51,098	32,061	172	94,5	169	98,3	47,535	32,257
END OF TREATMENT	Other	185	99,5	162	87,6	52,675	31,023	182	100,0	162	89,0	46,091	31,114
FU MONTH 18	Other	171	91,9	153	89,5	56,209	32,098	166	91,2	151	91,0	50,993	31,928
FU MONTH 24	Other	169	90,9	154	91,1	56,926	30,944	156	85,7	142	91,0	54,695	32,091
FU MONTH 36	Other	160	86,0	145	90,6	59,770	30,148	149	81,9	130	87,2	56,667	34,886
Protocol version													
BASELINE	Protocol A	1240	100,0	1193	96,2	50,796	31,898	1246	100,0	1201	96,4	49,570	32,117

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF ANTHRACYCLINE	Protocol A	984	79,4	910	92,5	52,894	31,633	988	79,3	925	93,6	49,405	31,724
WEEK 13	Protocol A	1155	93,1	1104	95,6	54,287	31,028	1180	94,7	1111	94,2	51,125	31,551
WEEK 25	Protocol A	1125	90,7	1083	96,3	58,326	30,757	1157	92,9	1088	94,0	55,576	30,256
END OF TREATMENT	Protocol A	1229	99,1	1068	86,9	61,517	29,708	1236	99,2	1111	89,9	57,216	30,865
FU MONTH 18	Protocol A	1142	92,1	1020	89,3	65,425	29,024	1156	92,8	995	86,1	60,034	29,311
FU MONTH 24	Protocol A	1124	90,6	985	87,6	66,464	28,749	1127	90,4	976	86,6	62,398	29,098
FU MONTH 36	Protocol A	1087	87,7	971	89,3	67,422	28,668	1069	85,8	927	86,7	63,287	30,207
BASELINE	Protocol Amendment B	571	100,0	553	96,8	52,080	31,409	577	100,0	560	97,1	52,321	31,122
END OF ANTHRACYCLINE	Protocol Amendment B	448	78,5	427	95,3	49,258	32,160	458	79,4	432	94,3	53,318	31,452
WEEK 13	Protocol Amendment B	533	93,3	495	92,9	52,593	31,343	545	94,5	523	96,0	53,920	29,740
WEEK 25	Protocol Amendment B	520	91,1	497	95,6	54,259	31,041	531	92,0	508	95,7	57,087	30,123
END OF TREATMENT	Protocol Amendment B	565	98,9	497	88,0	56,673	30,021	575	99,7	510	88,7	58,105	29,820
FU MONTH 18	Protocol Amendment B	521	91,2	455	87,3	60,440	29,063	532	92,2	466	87,6	60,658	29,688
FU MONTH 24	Protocol Amendment B	509	89,1	431	84,7	62,258	28,002	511	88,6	442	86,5	63,348	29,680
FU MONTH 36	Protocol Amendment B	484	84,8	409	84,5	62,999	28,964	487	84,4	415	85,2	65,382	30,091
Nodal status													
BASELINE	0 positive nodes	308	100,0	297	96,4	52,301	32,120	321	100,0	309	96,3	54,153	31,236
END OF ANTHRACYCLINE	0 positive nodes	223	72,4	208	93,3	53,686	30,689	229	71,3	216	94,3	51,698	32,584
WEEK 13	0 positive nodes	294	95,5	276	93,9	56,280	31,088	303	94,4	292	96,4	53,082	32,019
WEEK 25	0 positive nodes	287	93,2	281	97,9	58,007	32,369	294	91,6	282	95,9	56,028	29,713
END OF TREATMENT	0 positive nodes	305	99,0	268	87,9	62,189	28,789	318	99,1	291	91,5	60,137	30,060
FU MONTH 18	0 positive nodes	292	94,8	261	89,4	65,773	28,406	298	92,8	263	88,3	62,484	27,387

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	0 positive nodes	290	94,2	249	85,9	68,942	28,227	295	91,9	262	88,8	66,158	27,055
FU MONTH 36	0 positive nodes	283	91,9	256	90,5	67,448	28,458	290	90,3	262	90,3	63,486	29,801
BASELINE	>= 1 positive nodes	1503	100,0	1449	96,4	50,978	31,669	1502	100,0	1452	96,7	49,656	31,899
END OF ANTHRACYCLINE	>= 1 positive nodes	1209	80,4	1129	93,4	51,373	32,043	1217	81,0	1141	93,8	50,453	31,515
WEEK 13	>= 1 positive nodes	1394	92,7	1323	94,9	53,238	31,120	1422	94,7	1342	94,4	51,788	30,783
WEEK 25	>= 1 positive nodes	1358	90,4	1299	95,7	56,839	30,575	1394	92,8	1314	94,3	56,063	30,330
END OF TREATMENT	>= 1 positive nodes	1489	99,1	1297	87,1	59,522	30,095	1493	99,4	1330	89,1	56,917	30,617
FU MONTH 18	>= 1 positive nodes	1371	91,2	1214	88,5	63,482	29,264	1390	92,5	1198	86,2	59,738	29,840
FU MONTH 24	>= 1 positive nodes	1343	89,4	1167	86,9	64,382	28,602	1343	89,4	1156	86,1	61,909	29,708
FU MONTH 36	>= 1 positive nodes	1288	85,7	1124	87,3	65,807	28,902	1266	84,3	1080	85,3	64,043	30,279
Menopausal status at randomization													
BASELINE	Premenopausal	873	100,0	846	96,9	49,567	31,724	885	100,0	862	97,4	49,845	32,040
END OF ANTHRACYCLINE	Premenopausal	708	81,1	674	95,2	50,346	31,953	726	82,0	690	95,0	51,159	31,458
WEEK 13	Premenopausal	841	96,3	802	95,4	52,244	31,136	852	96,3	807	94,7	52,251	30,165
WEEK 25	Premenopausal	825	94,5	796	96,5	55,151	30,463	838	94,7	797	95,1	54,036	30,754
END OF TREATMENT	Premenopausal	866	99,2	760	87,8	58,377	29,785	881	99,5	808	91,7	56,601	30,061
FU MONTH 18	Premenopausal	819	93,8	716	87,4	61,732	29,137	835	94,4	735	88,0	58,912	29,354
FU MONTH 24	Premenopausal	803	92,0	700	87,2	62,286	29,295	807	91,2	705	87,4	61,749	29,103

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Premenopausal	765	87,6	664	86,8	65,161	28,966	773	87,3	665	86,0	63,459	29,380
BASELINE	Postmenopausal	933	100,0	895	95,9	52,663	31,690	929	100,0	891	95,9	51,104	31,638
END OF ANTHRACYCLINE	Postmenopausal	719	77,1	658	91,5	53,090	31,664	711	76,5	661	93,0	50,177	31,920
WEEK 13	Postmenopausal	842	90,2	793	94,2	55,233	31,084	864	93,0	819	94,8	51,893	31,792
WEEK 25	Postmenopausal	815	87,4	779	95,6	58,922	31,185	841	90,5	792	94,2	58,081	29,451
END OF TREATMENT	Postmenopausal	923	98,9	801	86,8	61,506	29,879	921	99,1	806	87,5	58,437	30,902
FU MONTH 18	Postmenopausal	839	89,9	756	90,1	65,961	29,005	844	90,9	720	85,3	61,667	29,307
FU MONTH 24	Postmenopausal	825	88,4	712	86,3	68,024	27,610	823	88,6	708	86,0	63,701	29,384
FU MONTH 36	Postmenopausal	801	85,9	712	88,9	66,994	28,696	776	83,5	673	86,7	64,537	30,867
BASELINE	Unknown/Missing	5	100,0	5	100,0	66,667	33,333	9	100,0	8	88,9	41,667	29,547
END OF ANTHRACYCLINE	Unknown/Missing	5	100,0	5	100,0	60,000	36,515	9	100,0	6	66,7	44,444	34,427
WEEK 13	Unknown/Missing	5	100,0	4	80,0	66,667	27,217	9	100,0	8	88,9	41,667	34,503
WEEK 25	Unknown/Missing	5	100,0	5	100,0	66,667	40,825	9	100,0	7	77,8	57,143	41,786
END OF TREATMENT	Unknown/Missing	5	100,0	4	80,0	58,333	41,944	9	100,0	7	77,8	52,381	42,414
FU MONTH 18	Unknown/Missing	5	100,0	3	60,0	55,556	19,245	9	100,0	6	66,7	50,000	45,947
FU MONTH 24	Unknown/Missing	5	100,0	4	80,0	66,667	27,217	8	88,9	5	62,5	53,333	38,006
FU MONTH 36	Unknown/Missing	5	100,0	4	80,0	66,667	27,217	7	77,8	4	57,1	41,667	41,944
Age II													
BASELINE	< 65	1581	100,0	1530	96,8	50,545	31,760	1604	100,0	1554	96,9	49,764	31,811
END OF ANTHRACYCLINE	< 65	1268	80,2	1192	94,0	51,818	31,749	1287	80,2	1215	94,4	50,672	31,661
WEEK 13	< 65	1497	94,7	1421	94,9	53,718	31,169	1529	95,3	1451	94,9	51,666	30,540

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	< 65	1464	92,6	1402	95,8	56,657	30,806	1501	93,6	1424	94,9	55,454	29,990
END OF TREATMENT	< 65	1569	99,2	1379	87,9	59,778	29,864	1596	99,5	1441	90,3	56,951	30,322
FU MONTH 18	< 65	1474	93,2	1304	88,5	63,062	29,402	1497	93,3	1305	87,2	59,796	29,416
FU MONTH 24	< 65	1446	91,5	1251	86,5	64,162	28,859	1450	90,4	1262	87,0	62,573	29,084
FU MONTH 36	< 65	1390	87,9	1222	87,9	66,012	28,990	1383	86,2	1197	86,6	63,631	30,067
BASELINE	>= 65	230	100,0	216	93,9	55,864	31,279	219	100,0	207	94,5	55,556	31,503
END OF ANTHRACYCLINE	>= 65	164	71,3	145	88,4	51,034	32,645	159	72,6	142	89,3	50,469	31,942
WEEK 13	>= 65	191	83,0	178	93,2	54,120	30,867	196	89,5	183	93,4	54,827	34,407
WEEK 25	>= 65	181	78,7	178	98,3	60,112	31,505	187	85,4	172	92,0	61,047	31,644
END OF TREATMENT	>= 65	225	97,8	186	82,7	61,470	30,063	215	98,2	180	83,7	61,852	31,930
FU MONTH 18	>= 65	189	82,2	171	90,5	70,175	26,085	191	87,2	156	81,7	63,889	29,319
FU MONTH 24	>= 65	187	81,3	165	88,2	72,929	25,125	188	85,8	156	83,0	63,675	30,847
FU MONTH 36	>= 65	181	78,7	158	87,3	66,878	27,517	173	79,0	145	83,8	66,437	31,056
Histological grade													
BASELINE	Grade 1	32	100,0	30	93,8	51,111	35,808	24	100,0	24	100,0	65,278	30,263
END OF ANTHRACYCLINE	Grade 1	18	56,3	16	88,9	60,417	34,894	17	70,8	16	94,1	56,250	29,107
WEEK 13	Grade 1	31	96,9	30	96,8	61,111	31,663	23	95,8	22	95,7	62,121	33,007
WEEK 25	Grade 1	31	96,9	28	90,3	55,952	32,778	23	95,8	22	95,7	59,091	27,084
END OF TREATMENT	Grade 1	31	96,9	27	87,1	59,259	32,467	24	100,0	22	91,7	59,091	28,971
FU MONTH 18	Grade 1	30	93,8	27	90,0	66,667	29,235	23	95,8	22	95,7	62,121	23,672
FU MONTH 24	Grade 1	28	87,5	27	96,4	66,667	29,235	23	95,8	21	91,3	71,429	28,452
FU MONTH 36	Grade 1	27	84,4	26	96,3	67,949	33,308	22	91,7	20	90,9	65,000	33,289
BASELINE	Grade 2	552	100,0	535	96,9	51,776	30,811	557	100,0	540	96,9	51,667	31,900
END OF ANTHRACYCLINE	Grade 2	445	80,6	423	95,1	50,827	31,859	446	80,1	420	94,2	51,429	30,735

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 13	Grade 2	507	91,8	485	95,7	53,814	31,305	524	94,1	503	96,0	52,618	29,853
WEEK 25	Grade 2	494	89,5	477	96,6	58,560	30,777	515	92,5	492	95,5	57,791	29,864
END OF TREATMENT	Grade 2	548	99,3	485	88,5	61,375	30,257	553	99,3	494	89,3	58,974	29,712
FU MONTH 18	Grade 2	507	91,8	454	89,5	65,419	29,895	517	92,8	446	86,3	62,257	28,142
FU MONTH 24	Grade 2	501	90,8	446	89,0	66,517	28,704	500	89,8	429	85,8	64,413	28,598
FU MONTH 36	Grade 2	487	88,2	435	89,3	67,969	28,096	476	85,5	411	86,3	65,937	29,115
BASELINE	Grade 3	1161	100,0	1118	96,3	50,686	32,149	1173	100,0	1129	96,2	49,365	31,602
END OF ANTHRACYCLINE	Grade 3	918	79,1	850	92,6	51,843	31,701	919	78,3	859	93,5	50,213	32,242
WEEK 13	Grade 3	1088	93,7	1023	94,0	53,242	30,756	1114	95,0	1049	94,2	51,350	31,410
WEEK 25	Grade 3	1059	91,2	1017	96,0	56,178	30,620	1087	92,7	1021	93,9	54,913	30,591
END OF TREATMENT	Grade 3	1150	99,1	992	86,3	59,341	29,384	1165	99,3	1045	89,7	56,651	31,046
FU MONTH 18	Grade 3	1067	91,9	940	88,1	63,191	28,445	1085	92,5	934	86,1	59,136	30,151
FU MONTH 24	Grade 3	1046	90,1	889	85,0	64,679	28,427	1053	89,8	913	86,7	61,847	29,430
FU MONTH 36	Grade 3	1002	86,3	867	86,5	65,283	28,712	999	85,2	860	86,1	63,140	30,757
BASELINE	Unevaluable/Unknown/Missing	66	100,0	63	95,5	55,556	30,527	69	100,0	68	98,6	53,431	34,139
END OF ANTHRACYCLINE	Unevaluable/Unknown/Missing	51	77,3	48	94,1	54,861	33,326	64	92,8	62	96,9	50,000	31,217
WEEK 13	Unevaluable/Unknown/Missing	62	93,9	61	98,4	58,470	35,306	64	92,8	60	93,8	55,000	32,373
WEEK 25	Unevaluable/Unknown/Missing	61	92,4	58	95,1	60,345	35,572	63	91,3	61	96,8	60,109	27,094
END OF TREATMENT	Unevaluable/Unknown/Missing	65	98,5	61	93,8	59,563	33,947	69	100,0	60	87,0	59,444	28,846
FU MONTH 18	Unevaluable/Unknown/Missing	59	89,4	54	91,5	61,728	33,899	63	91,3	59	93,7	61,582	28,910

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 24	Unevaluable/Unknown/Missing	58	87,9	54	93,1	61,728	29,960	62	89,9	55	88,7	60,000	31,688
FU MONTH 36	Unevaluable/Unknown/Missing	55	83,3	52	94,5	63,462	33,826	59	85,5	51	86,4	60,784	27,249
Type of surgery for primary tumor													
BASELINE	Breast conserving surgery	728	100,0	698	95,9	50,000	31,804	715	100,0	676	94,5	49,901	31,505
END OF ANTHRACYCLINE	Breast conserving surgery	592	81,3	543	91,7	51,565	31,969	572	80,0	519	90,7	51,381	31,167
WEEK 13	Breast conserving surgery	677	93,0	636	93,9	53,354	31,319	673	94,1	631	93,8	52,139	30,201
WEEK 25	Breast conserving surgery	665	91,3	636	95,6	56,971	31,280	654	91,5	612	93,6	55,610	30,324
END OF TREATMENT	Breast conserving surgery	722	99,2	620	85,9	60,269	29,963	711	99,4	617	86,8	57,536	31,056
FU MONTH 18	Breast conserving surgery	678	93,1	591	87,2	63,734	29,669	659	92,2	552	83,8	61,594	29,075
FU MONTH 24	Breast conserving surgery	666	91,5	564	84,7	65,898	28,191	644	90,1	553	85,9	63,894	29,082
FU MONTH 36	Breast conserving surgery	651	89,4	554	85,1	67,870	27,678	616	86,2	533	86,5	64,040	29,501
BASELINE	Mastectomy	1083	100,0	1048	96,8	52,004	31,688	1107	100,0	1084	97,9	50,830	32,004
END OF ANTHRACYCLINE	Mastectomy	840	77,6	794	94,5	51,847	31,763	873	78,9	837	95,9	50,259	31,974
WEEK 13	Mastectomy	1011	93,4	963	95,3	54,033	31,012	1051	94,9	1002	95,3	51,929	31,522
WEEK 25	Mastectomy	980	90,5	944	96,3	57,097	30,648	1033	93,3	983	95,2	56,358	30,161
END OF TREATMENT	Mastectomy	1072	99,0	945	88,2	59,788	29,845	1099	99,3	1003	91,3	57,494	30,229
FU MONTH 18	Mastectomy	985	91,0	884	89,7	63,989	28,759	1028	92,9	908	88,3	59,471	29,569
FU MONTH 24	Mastectomy	967	89,3	852	88,1	64,710	28,841	993	89,7	864	87,0	61,998	29,328

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 36	Mastectomy	920	84,9	826	89,8	64,931	29,514	939	84,8	809	86,2	63,865	30,631
BASELINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
END OF ANTHRACYCLINE	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
WEEK 13	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	66,667	NE
WEEK 25	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
END OF TREATMENT	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	33,333	NE
FU MONTH 18	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 24	Missing	0	0,0	0	0,0	NE	NE	1	100,0	1	100,0	0,000	NE
FU MONTH 36	Missing	0	0,0	0	0,0	NE	NE	1	100,0	0	0,0	NE	NE
Tumor size													
BASELINE	0 - < 2 cm	660	100,0	642	97,3	49,896	31,392	665	100,0	634	95,3	50,210	30,971
END OF ANTHRACYCLINE	0 - < 2 cm	519	78,6	480	92,5	50,556	31,430	523	78,6	490	93,7	49,252	31,700
WEEK 13	0 - < 2 cm	620	93,9	579	93,4	54,174	30,429	631	94,9	606	96,0	52,585	30,055
WEEK 25	0 - < 2 cm	608	92,1	580	95,4	57,529	30,521	617	92,8	588	95,3	56,859	29,957
END OF TREATMENT	0 - < 2 cm	655	99,2	574	87,6	60,453	28,301	661	99,4	596	90,2	59,060	28,891
FU MONTH 18	0 - < 2 cm	617	93,5	545	88,3	63,792	27,894	624	93,8	557	89,3	61,640	28,601
FU MONTH 24	0 - < 2 cm	607	92,0	526	86,7	66,350	26,784	606	91,1	527	87,0	64,326	28,644
FU MONTH 36	0 - < 2 cm	596	90,3	522	87,6	67,433	27,851	580	87,2	503	86,7	65,673	29,401
BASELINE	>= 2 - < 5 cm	1009	100,0	967	95,8	52,154	31,954	991	100,0	963	97,2	49,844	32,504
END OF ANTHRACYCLINE	>= 2 - < 5 cm	797	79,0	750	94,1	52,889	32,221	789	79,6	742	94,0	50,854	31,767
WEEK 13	>= 2 - < 5 cm	935	92,7	893	95,5	53,602	31,426	940	94,9	887	94,4	51,447	31,076
WEEK 25	>= 2 - < 5 cm	910	90,2	878	96,5	56,720	31,149	919	92,7	859	93,5	55,374	30,160
END OF TREATMENT	>= 2 - < 5 cm	998	98,9	863	86,5	60,371	30,638	985	99,4	874	88,7	56,140	31,119

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
FU MONTH 18	>= 2 - < 5 cm	923	91,5	822	89,1	64,882	29,606	914	92,2	774	84,7	59,388	30,190
FU MONTH 24	>= 2 - < 5 cm	905	89,7	777	85,9	64,865	29,644	889	89,7	773	87,0	61,449	29,680
FU MONTH 36	>= 2 - < 5 cm	857	84,9	755	88,1	65,916	28,998	839	84,7	722	86,1	63,112	30,478
BASELINE	>= 5 cm	139	100,0	135	97,1	50,864	31,761	165	100,0	162	98,2	55,144	30,708
END OF ANTHRACYCLINE	>= 5 cm	113	81,3	104	92,0	49,359	30,804	132	80,0	123	93,2	55,014	31,066
WEEK 13	>= 5 cm	130	93,5	124	95,4	52,957	32,374	152	92,1	139	91,4	53,237	34,687
WEEK 25	>= 5 cm	124	89,2	119	96,0	56,863	31,098	150	90,9	147	98,0	57,143	31,454
END OF TREATMENT	>= 5 cm	138	99,3	125	90,6	55,200	31,425	163	98,8	149	91,4	59,508	33,008
FU MONTH 18	>= 5 cm	120	86,3	105	87,5	56,508	30,705	148	89,7	128	86,5	59,375	28,351
FU MONTH 24	>= 5 cm	118	84,9	110	93,2	61,818	29,205	141	85,5	116	82,3	64,080	28,876
FU MONTH 36	>= 5 cm	115	82,7	100	87,0	60,667	31,916	135	81,8	115	85,2	62,029	31,184
BASELINE	Missing	3	100,0	2	66,7	33,333	47,140	2	100,0	2	100,0	33,333	47,140
END OF ANTHRACYCLINE	Missing	3	100,0	3	100,0	33,333	33,333	2	100,0	2	100,0	50,000	23,570
WEEK 13	Missing	3	100,0	3	100,0	55,556	38,490	2	100,0	2	100,0	50,000	23,570
WEEK 25	Missing	3	100,0	3	100,0	66,667	33,333	2	100,0	2	100,0	33,333	47,140
END OF TREATMENT	Missing	3	100,0	3	100,0	55,556	38,490	2	100,0	2	100,0	33,333	47,140
FU MONTH 18	Missing	3	100,0	3	100,0	66,667	33,333	2	100,0	2	100,0	50,000	23,570
FU MONTH 24	Missing	3	100,0	3	100,0	66,667	33,333	2	100,0	2	100,0	33,333	47,140
FU MONTH 36	Missing	3	100,0	3	100,0	66,667	33,333	2	100,0	2	100,0	33,333	47,140
Loco-regional radiotherapy													
BASELINE	Yes	1347	100,0	1311	97,3	50,775	31,784	1350	100,0	1300	96,3	49,692	31,782
END OF ANTHRACYCLINE	Yes	1103	81,9	1041	94,4	51,777	31,577	1104	81,8	1038	94,0	50,963	31,407
WEEK 13	Yes	1308	97,1	1239	94,7	53,484	31,079	1324	98,1	1247	94,2	51,778	30,719
WEEK 25	Yes	1277	94,8	1222	95,7	57,147	30,724	1302	96,4	1223	93,9	56,119	30,252

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
END OF TREATMENT	Yes	1347	100,0	1206	89,5	59,563	29,632	1350	100,0	1230	91,1	57,344	30,542
FU MONTH 18	Yes	1291	95,8	1138	88,1	63,679	29,072	1298	96,1	1120	86,3	60,238	29,465
FU MONTH 24	Yes	1266	94,0	1095	86,5	65,053	28,477	1260	93,3	1085	86,1	62,366	29,516
FU MONTH 36	Yes	1219	90,5	1052	86,3	66,508	28,064	1195	88,5	1027	85,9	64,038	30,136
BASELINE	No	464	100,0	435	93,8	52,490	31,612	473	100,0	461	97,5	52,567	31,871
END OF ANTHRACYCLINE	No	329	70,9	296	90,0	51,577	32,783	342	72,3	319	93,3	49,634	32,576
WEEK 13	No	380	81,9	360	94,7	54,722	31,312	401	84,8	387	96,5	52,799	31,923
WEEK 25	No	368	79,3	358	97,3	56,704	31,510	386	81,6	373	96,6	55,853	30,121
END OF TREATMENT	No	447	96,3	359	80,3	61,374	30,714	461	97,5	391	84,8	57,971	30,541
FU MONTH 18	No	372	80,2	337	90,6	64,590	29,305	390	82,5	341	87,4	60,215	29,329
FU MONTH 24	No	367	79,1	321	87,5	65,628	28,969	378	79,9	333	88,1	63,764	28,487
FU MONTH 36	No	352	75,9	328	93,2	64,837	31,120	361	76,3	315	87,3	63,598	30,351
Race													
BASELINE	White	1252	100,0	1193	95,3	48,449	32,162	1255	100,0	1203	95,9	47,382	31,791
END OF ANTHRACYCLINE	White	1010	80,7	926	91,7	50,108	31,831	1018	81,1	936	91,9	48,860	31,574
WEEK 13	White	1158	92,5	1079	93,2	51,869	31,265	1183	94,3	1094	92,5	49,695	31,132
WEEK 25	White	1120	89,5	1058	94,5	55,482	30,756	1150	91,6	1067	92,8	54,577	30,707
END OF TREATMENT	White	1238	98,9	1040	84,0	57,788	30,698	1244	99,1	1082	87,0	54,960	31,257
FU MONTH 18	White	1138	90,9	973	85,5	62,830	29,805	1152	91,8	953	82,7	58,867	30,111
FU MONTH 24	White	1115	89,1	925	83,0	63,784	29,159	1120	89,2	936	83,6	60,897	30,366
FU MONTH 36	White	1071	85,5	912	85,2	65,314	29,458	1064	84,8	889	83,6	62,392	30,825
BASELINE	Black	25	100,0	24	96,0	59,722	31,051	31	100,0	29	93,5	47,126	39,357
END OF ANTHRACYCLINE	Black	9	36,0	9	100,0	48,148	33,793	15	48,4	15	100,0	42,222	36,659
WEEK 13	Black	21	84,0	17	81,0	64,706	32,212	29	93,5	28	96,6	57,143	37,248

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Black	21	84,0	19	90,5	61,404	35,596	29	93,5	28	96,6	60,714	37,464
END OF TREATMENT	Black	24	96,0	22	91,7	71,212	33,007	31	100,0	28	90,3	59,524	35,552
FU MONTH 18	Black	23	92,0	17	73,9	74,510	25,082	29	93,5	24	82,8	50,000	36,778
FU MONTH 24	Black	22	88,0	18	81,8	74,074	31,427	28	90,3	23	82,1	66,667	36,237
FU MONTH 36	Black	22	88,0	18	81,8	66,667	32,338	26	83,9	20	76,9	53,333	43,796
BASELINE	Asian	477	100,0	473	99,2	57,153	29,690	484	100,0	478	98,8	58,717	29,390
END OF ANTHRACYCLINE	Asian	370	77,6	359	97,0	55,060	31,390	375	77,5	368	98,1	55,797	30,679
WEEK 13	Asian	455	95,4	449	98,7	56,941	29,913	466	96,3	465	99,8	57,061	28,842
WEEK 25	Asian	450	94,3	449	99,8	59,540	30,435	465	96,1	459	98,7	59,477	28,194
END OF TREATMENT	Asian	475	99,6	452	95,2	63,717	27,298	484	100,0	463	95,7	63,355	27,014
FU MONTH 18	Asian	447	93,7	432	96,6	65,355	27,074	461	95,2	443	96,1	63,281	27,113
FU MONTH 24	Asian	442	92,7	424	95,9	67,138	26,824	445	91,9	418	93,9	66,268	25,755
FU MONTH 36	Asian	424	88,9	402	94,8	67,413	27,291	425	87,8	398	93,6	67,420	27,428
BASELINE	Other	52	100,0	51	98,1	58,170	30,436	51	100,0	50	98,0	46,667	36,886
END OF ANTHRACYCLINE	Other	38	73,1	38	100,0	63,158	29,804	36	70,6	36	100,0	47,222	37,691
WEEK 13	Other	49	94,2	49	100,0	63,946	33,220	45	88,2	45	100,0	51,852	38,636
WEEK 25	Other	49	94,2	49	100,0	68,027	31,885	42	82,4	40	95,2	51,667	31,078
END OF TREATMENT	Other	52	100,0	47	90,4	69,504	27,654	50	98,0	47	94,0	56,028	35,513
FU MONTH 18	Other	50	96,2	48	96,0	68,750	31,814	44	86,3	39	88,6	64,103	29,995
FU MONTH 24	Other	49	94,2	45	91,8	71,852	28,387	43	84,3	39	90,7	63,248	30,392
FU MONTH 36	Other	49	94,2	43	87,8	70,543	25,416	39	76,5	33	84,6	68,687	31,113
BASELINE	Missing	5	100,0	5	100,0	33,333	47,140	2	100,0	1	50,0	66,667	NE
END OF ANTHRACYCLINE	Missing	5	100,0	5	100,0	33,333	47,140	2	100,0	2	100,0	66,667	0,000
WEEK 13	Missing	5	100,0	5	100,0	40,000	43,461	2	100,0	2	100,0	83,333	23,570

		PERTUZUMAB (N=1811)						PLACEBO (N=1823)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
WEEK 25	Missing	5	100,0	5	100,0	40,000	43,461	2	100,0	2	100,0	83,333	23,570
END OF TREATMENT	Missing	5	100,0	4	80,0	33,333	27,217	2	100,0	1	50,0	100,000	NE
FU MONTH 18	Missing	5	100,0	5	100,0	60,000	43,461	2	100,0	2	100,0	83,333	23,570
FU MONTH 24	Missing	5	100,0	4	80,0	66,667	47,140	2	100,0	2	100,0	100,000	0,000
FU MONTH 36	Missing	5	100,0	5	100,0	66,667	47,140	2	100,0	2	100,0	83,333	23,570

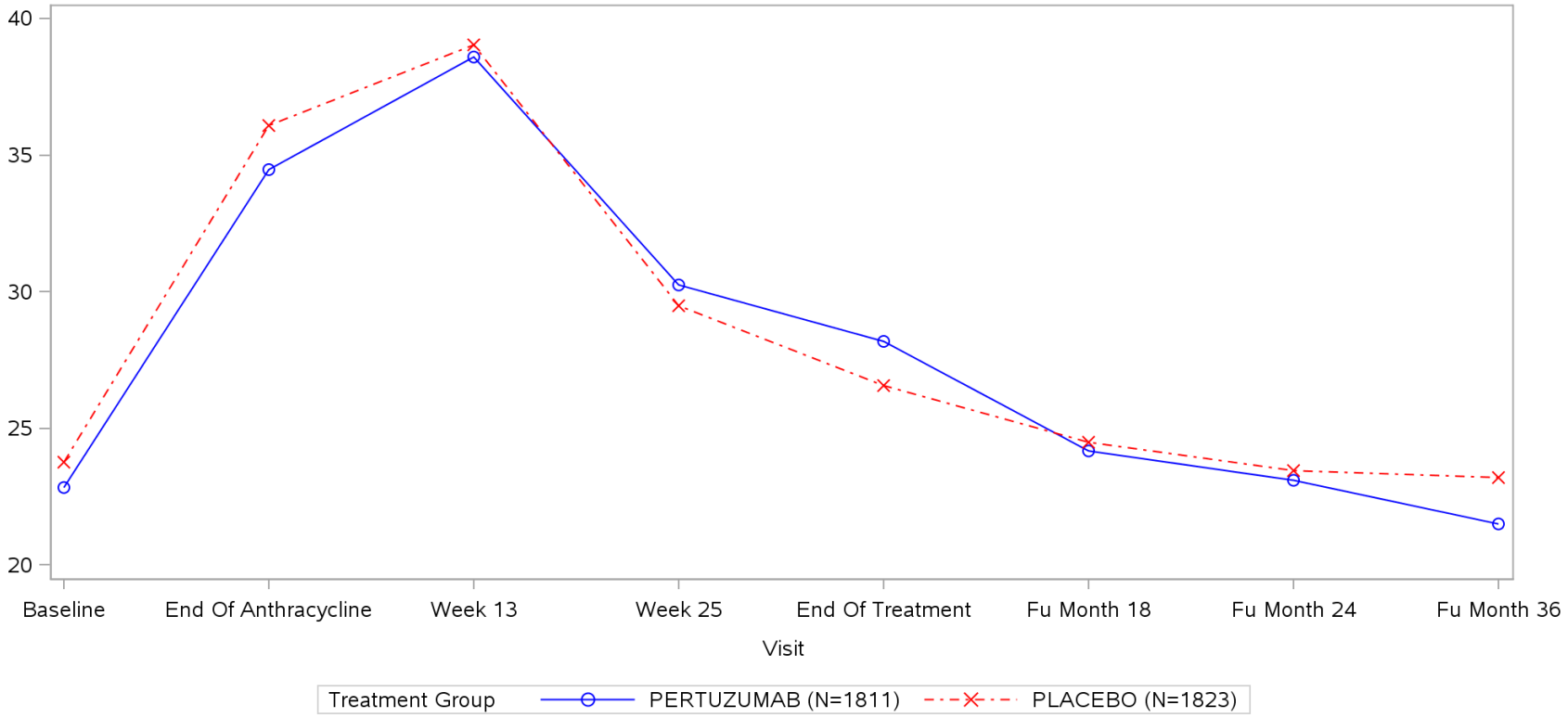
[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_26a_19DEC2016_CHON_FSC09_SG.xls
11AUG2020 16:01

Patientenberichtete Endpunkte (Datenschnitt: 19.12.2016)

Mean Plots

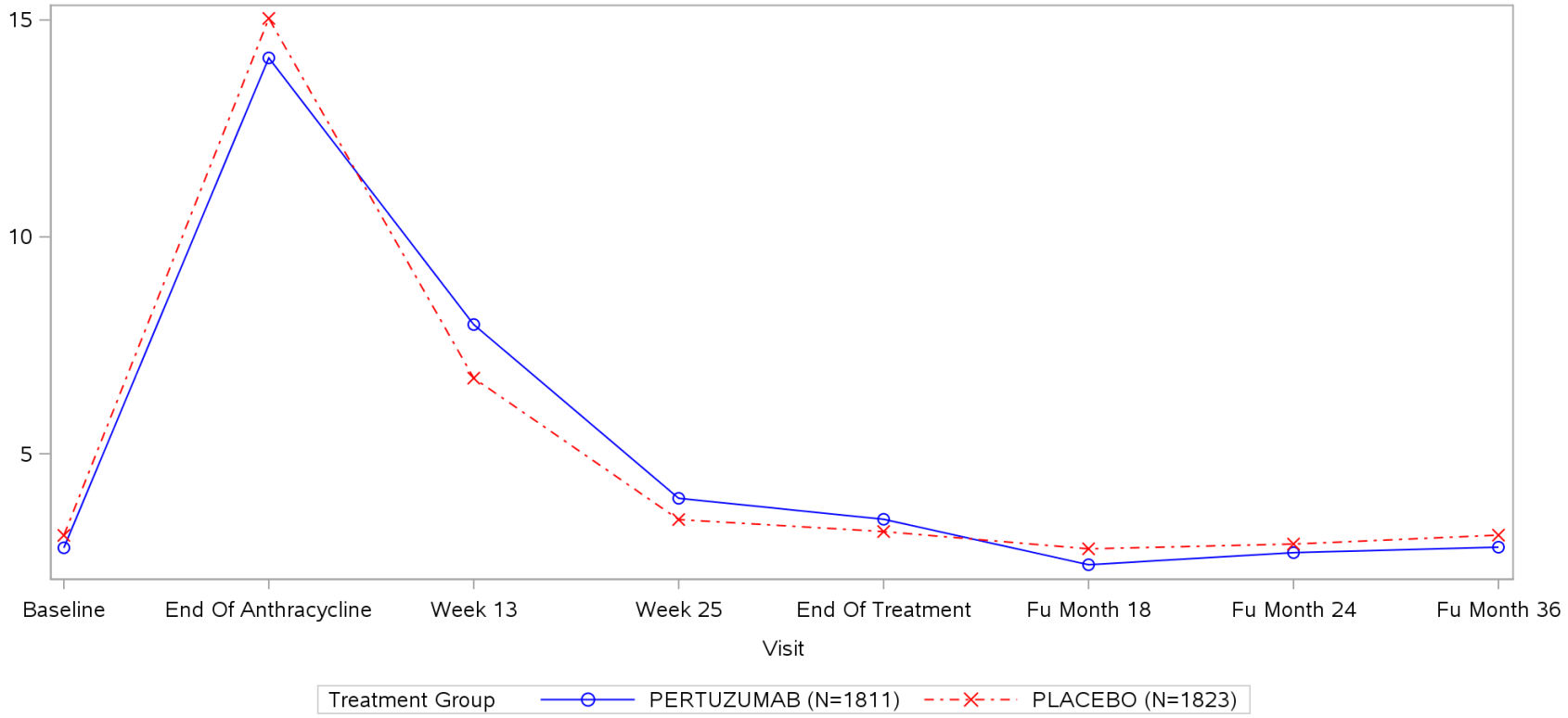
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Fatigue Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC01.pdf
30MAR2020 11:22

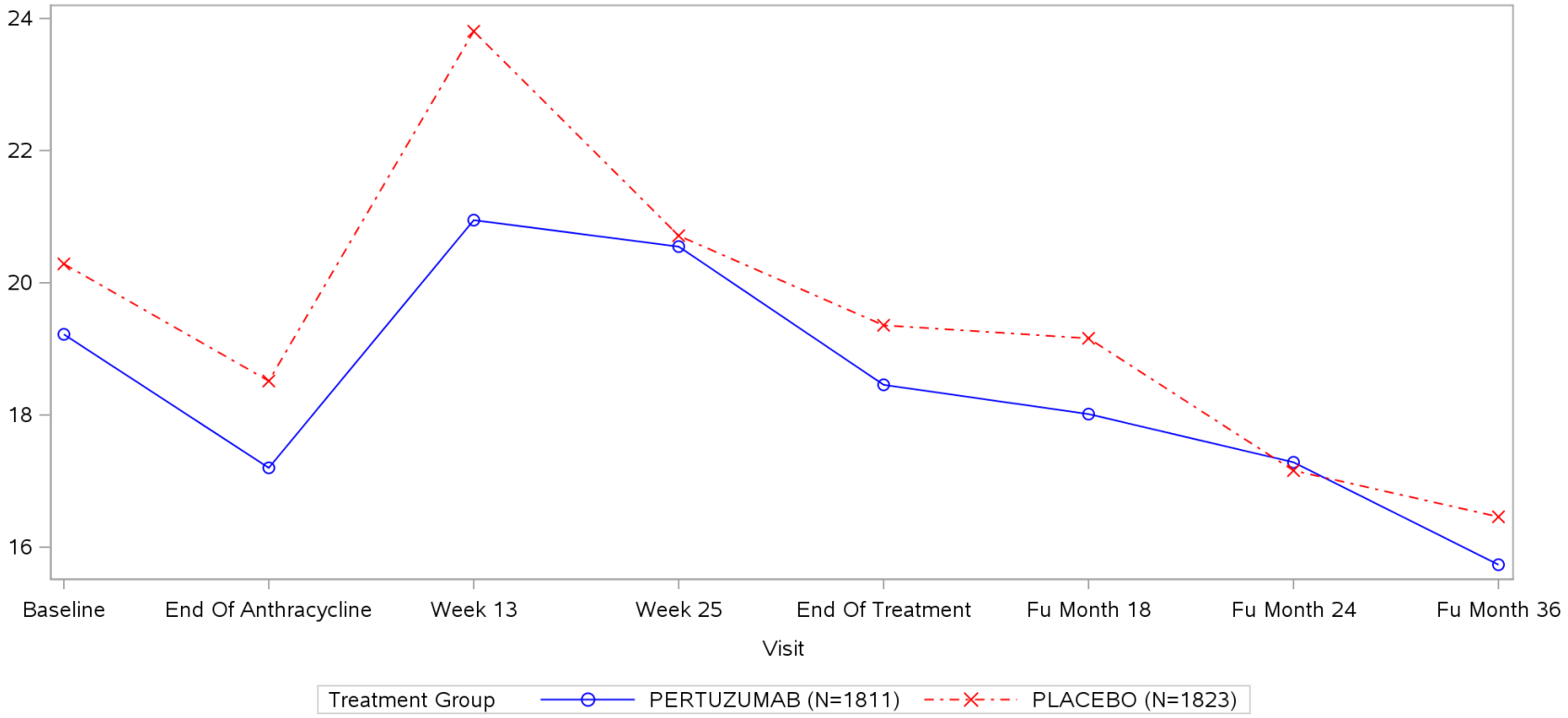
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Nausea/Vomiting Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC02.pdf
30MAR2020 11:22

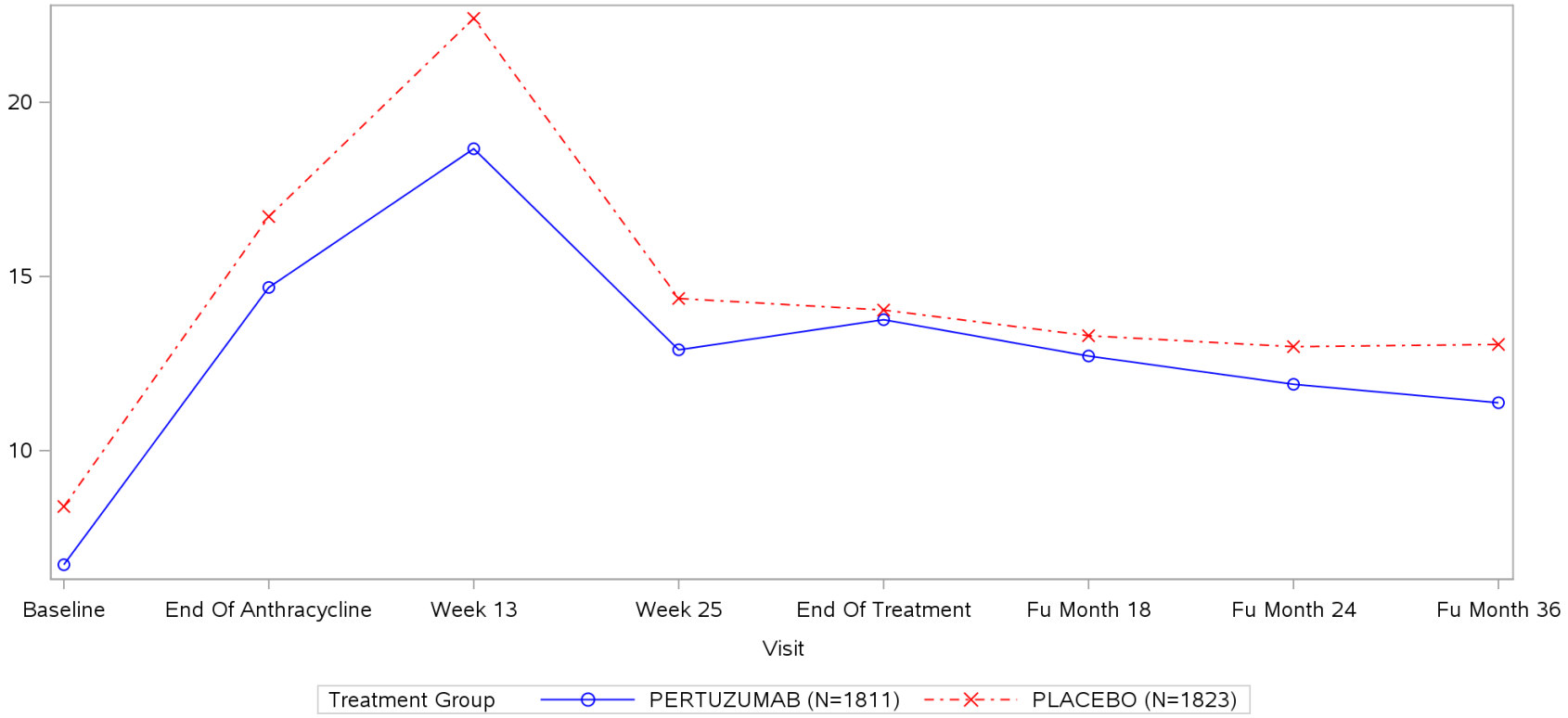
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Pain Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC03.pdf
30MAR2020 11:23

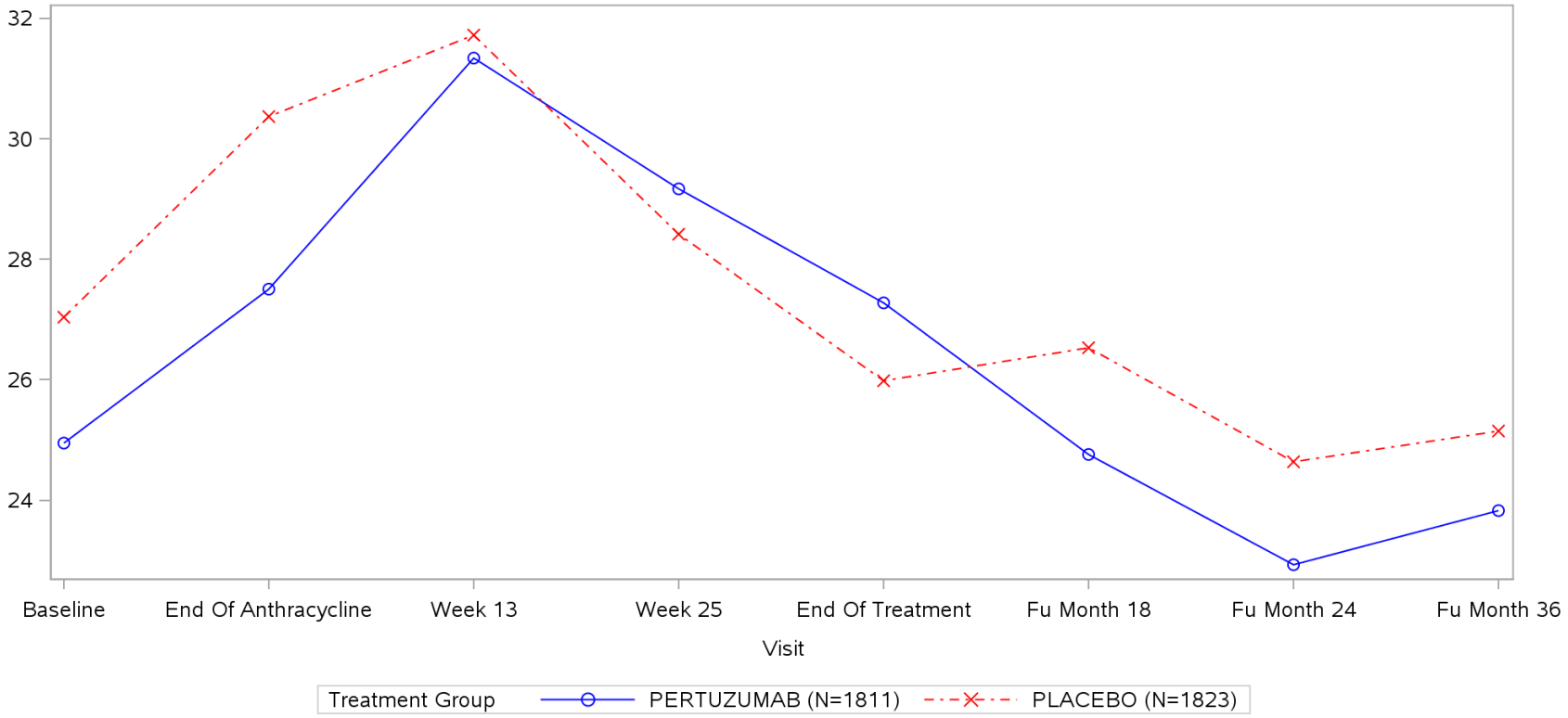
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Dyspnea Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC04.pdf
30MAR2020 11:24

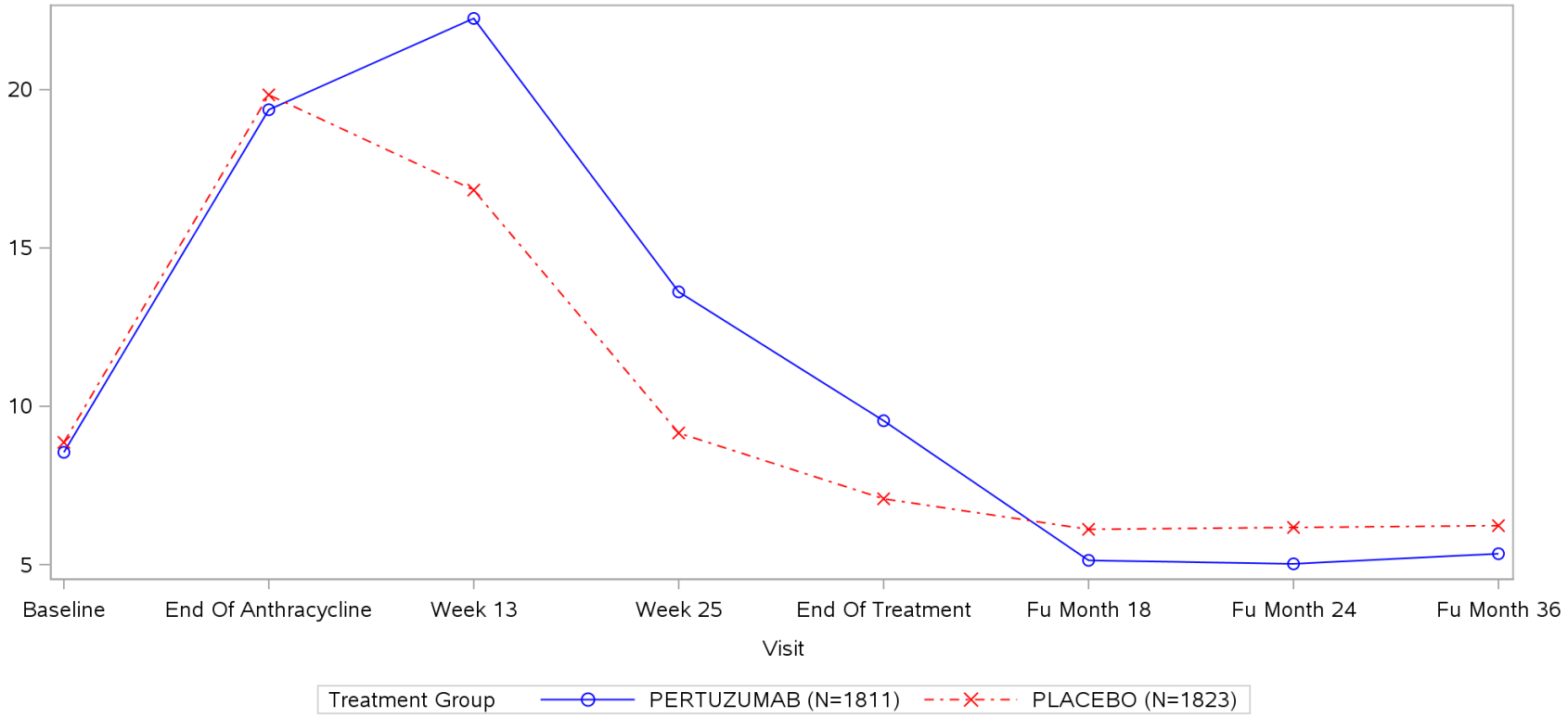
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Insomnia Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC05.pdf
30MAR2020 11:25

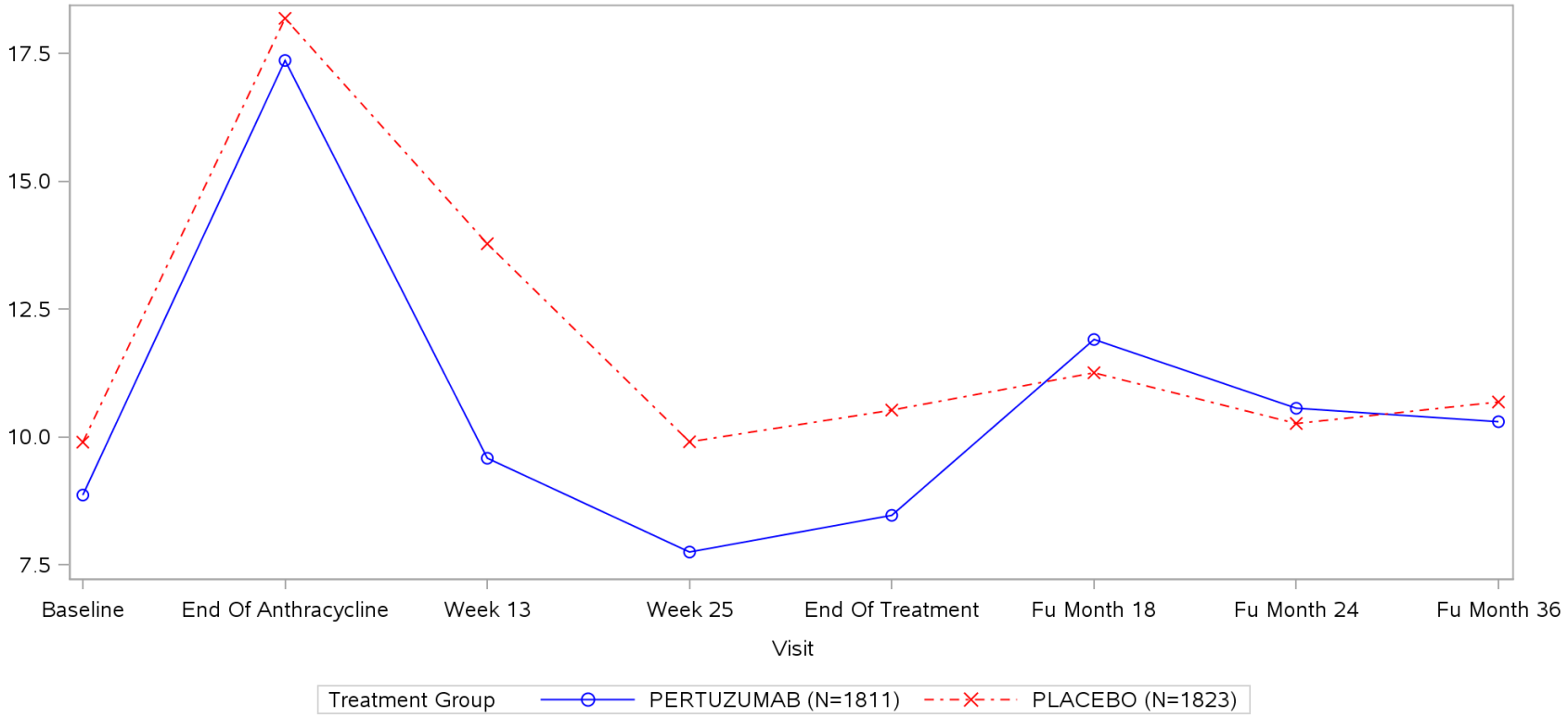
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Appetite Loss Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC06.pdf
30MAR2020 11:25

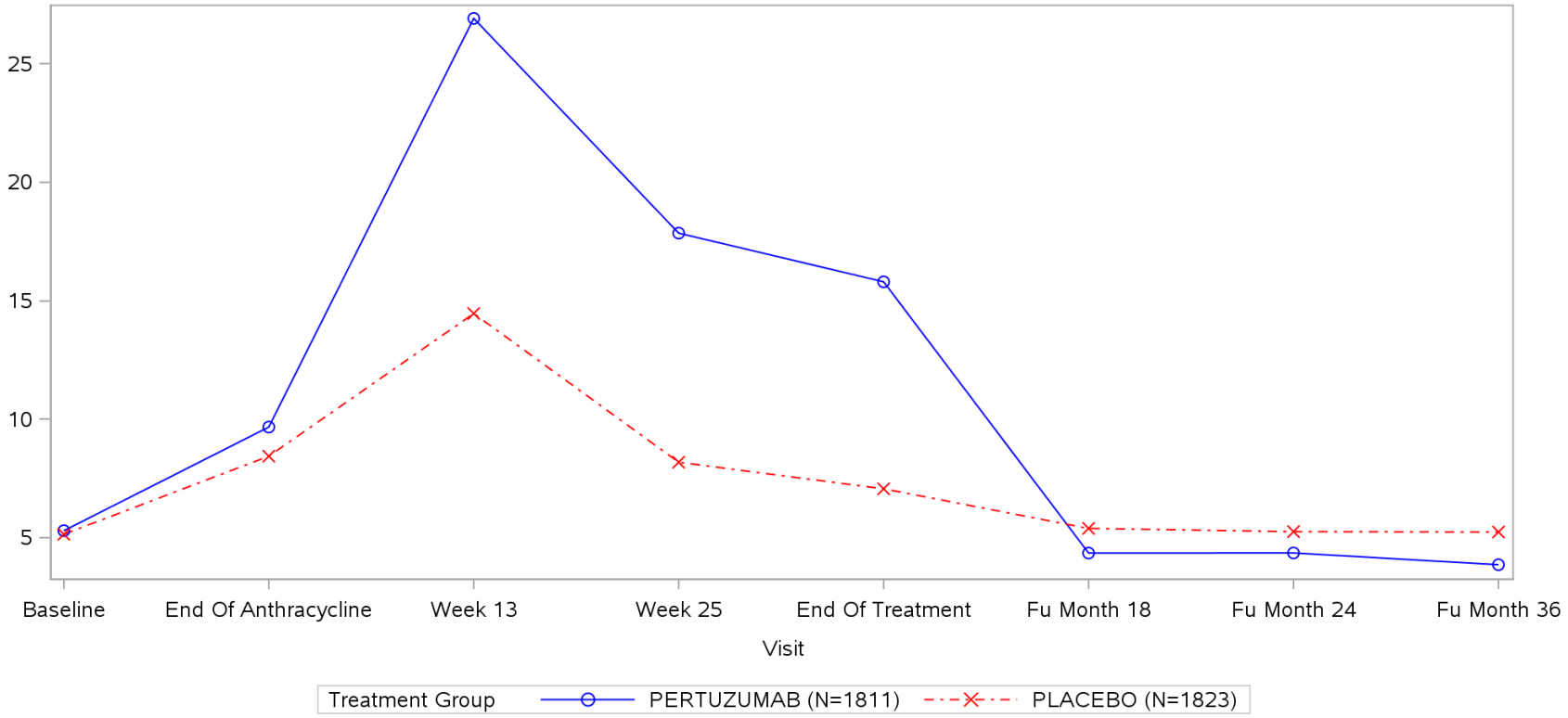
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Constipation Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC07.pdf
30MAR2020 11:26

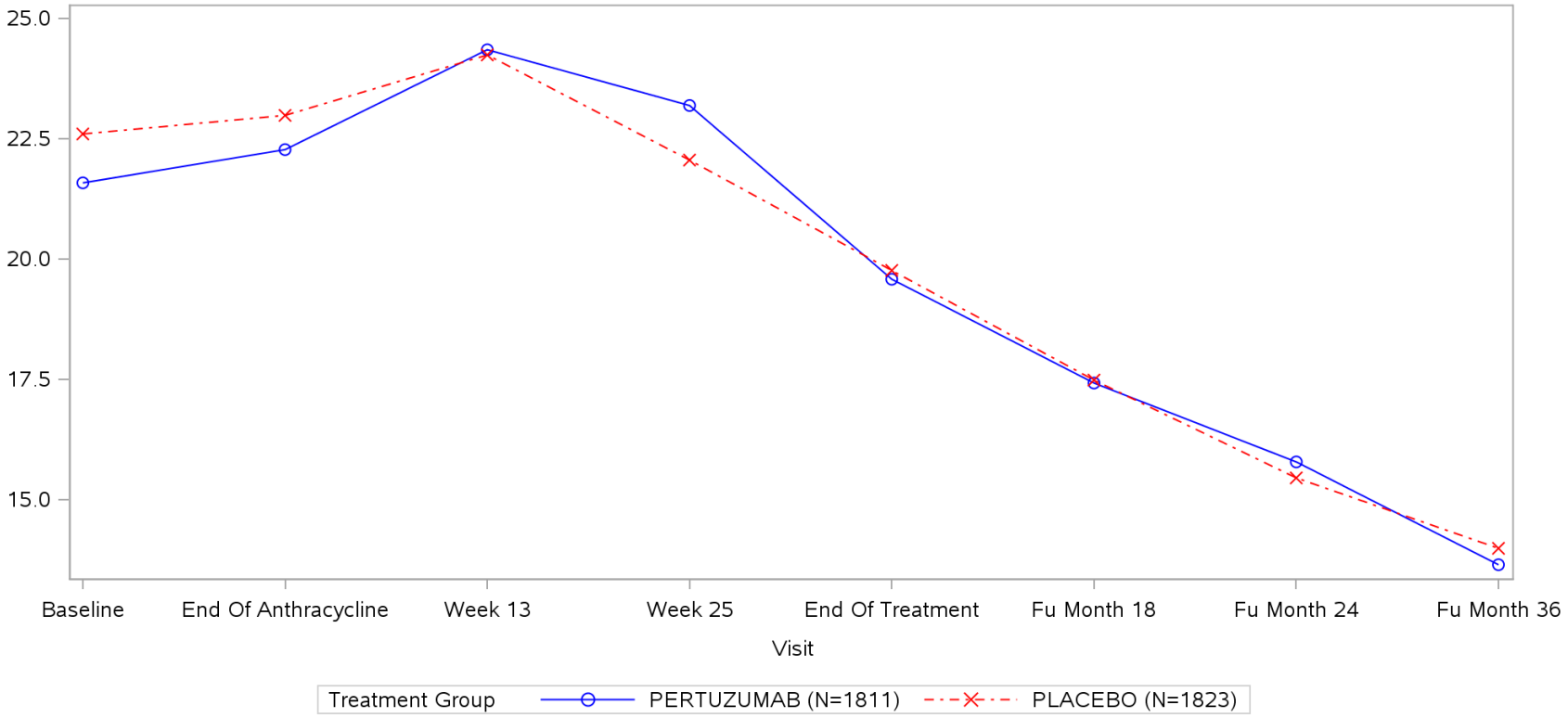
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Diarrhea Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC08.pdf
30MAR2020 11:27

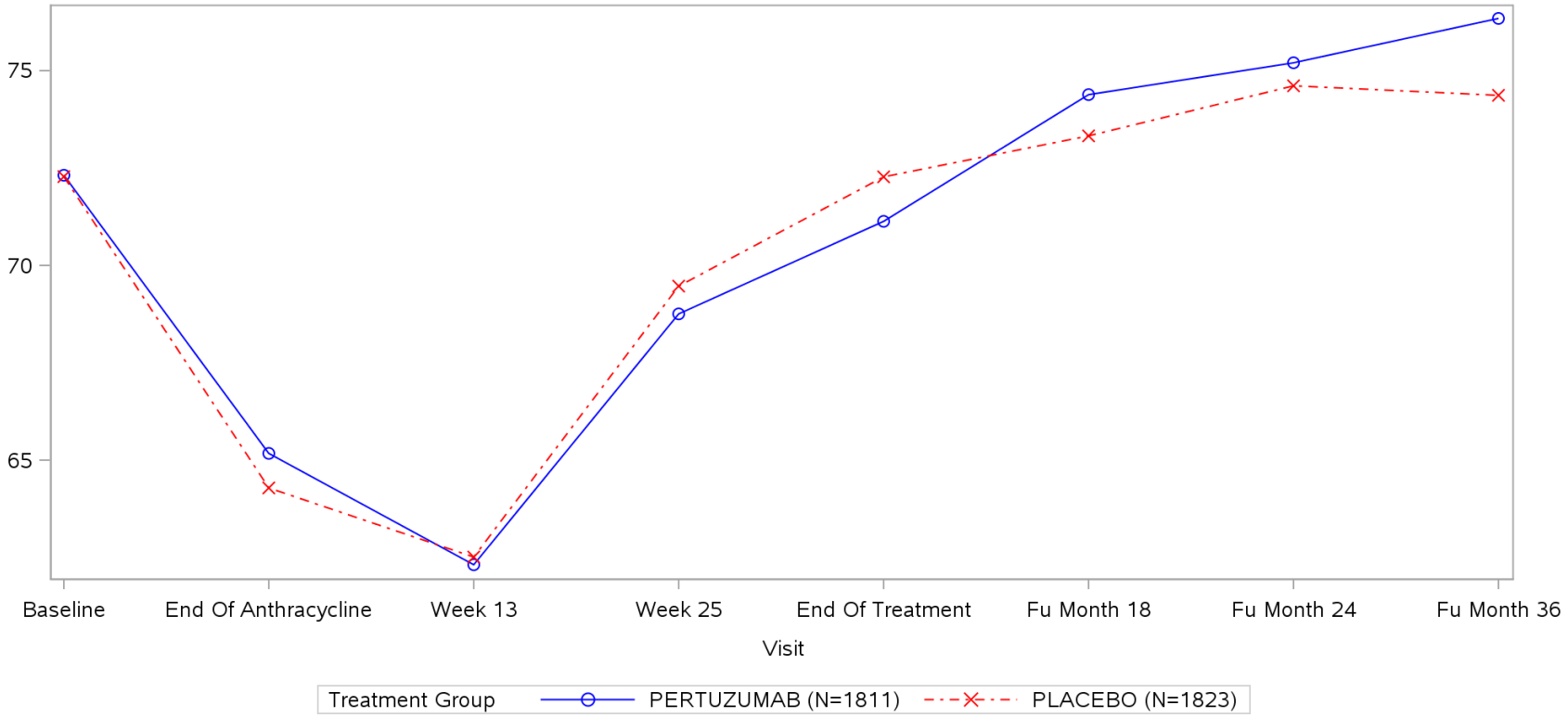
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Financial Difficulties Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC09.pdf
30MAR2020 11:27

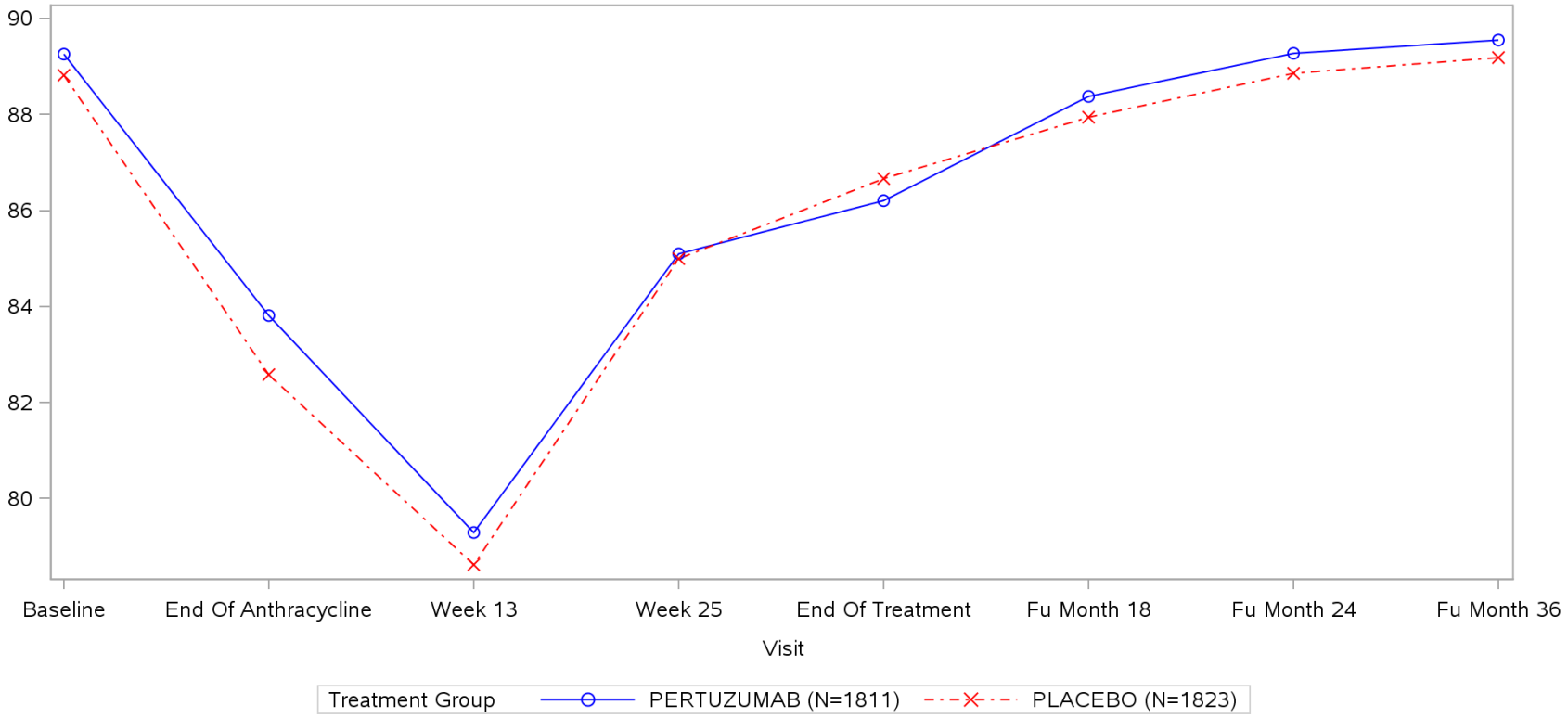
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Global Health Status
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_GLHST.pdf
30MAR2020 11:21

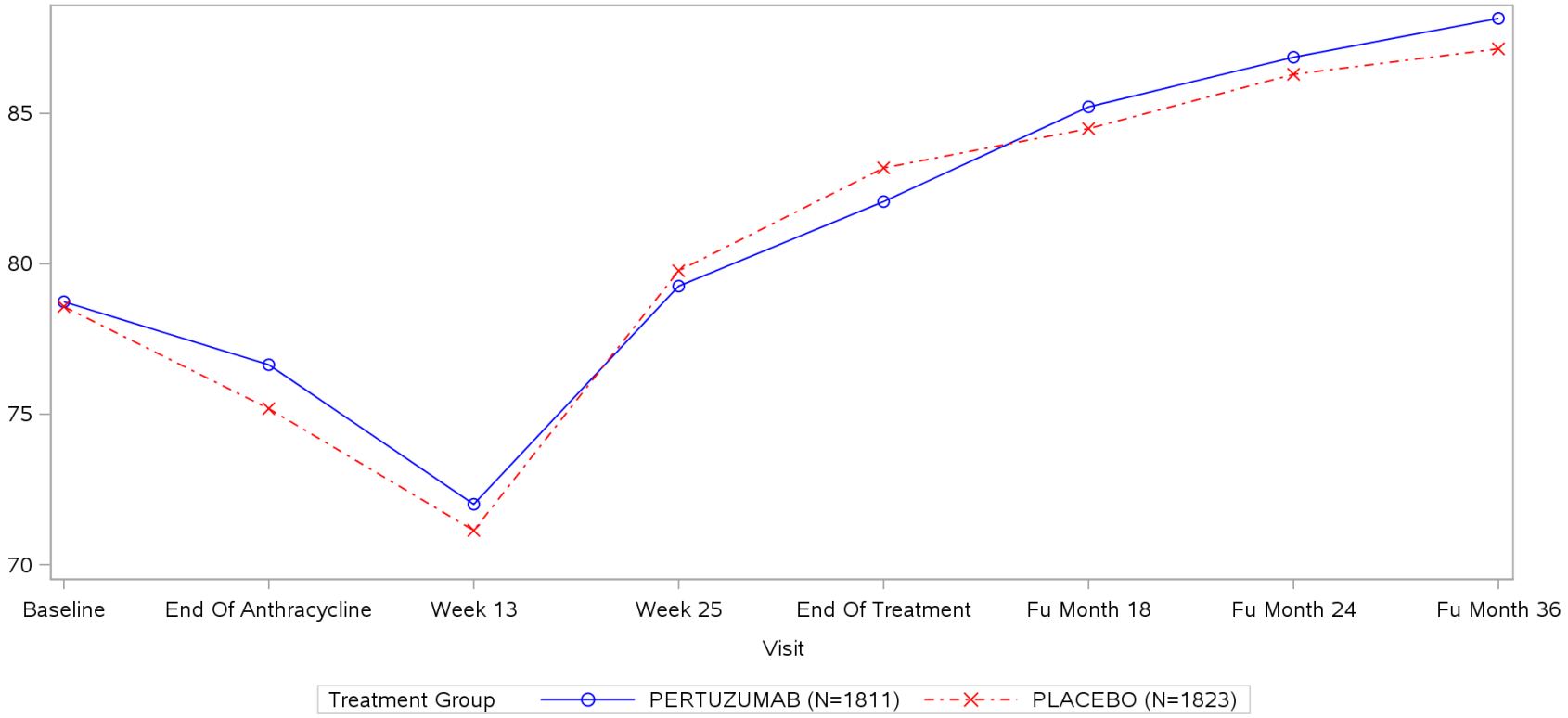
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Physical Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC01.pdf
30MAR2020 11:14

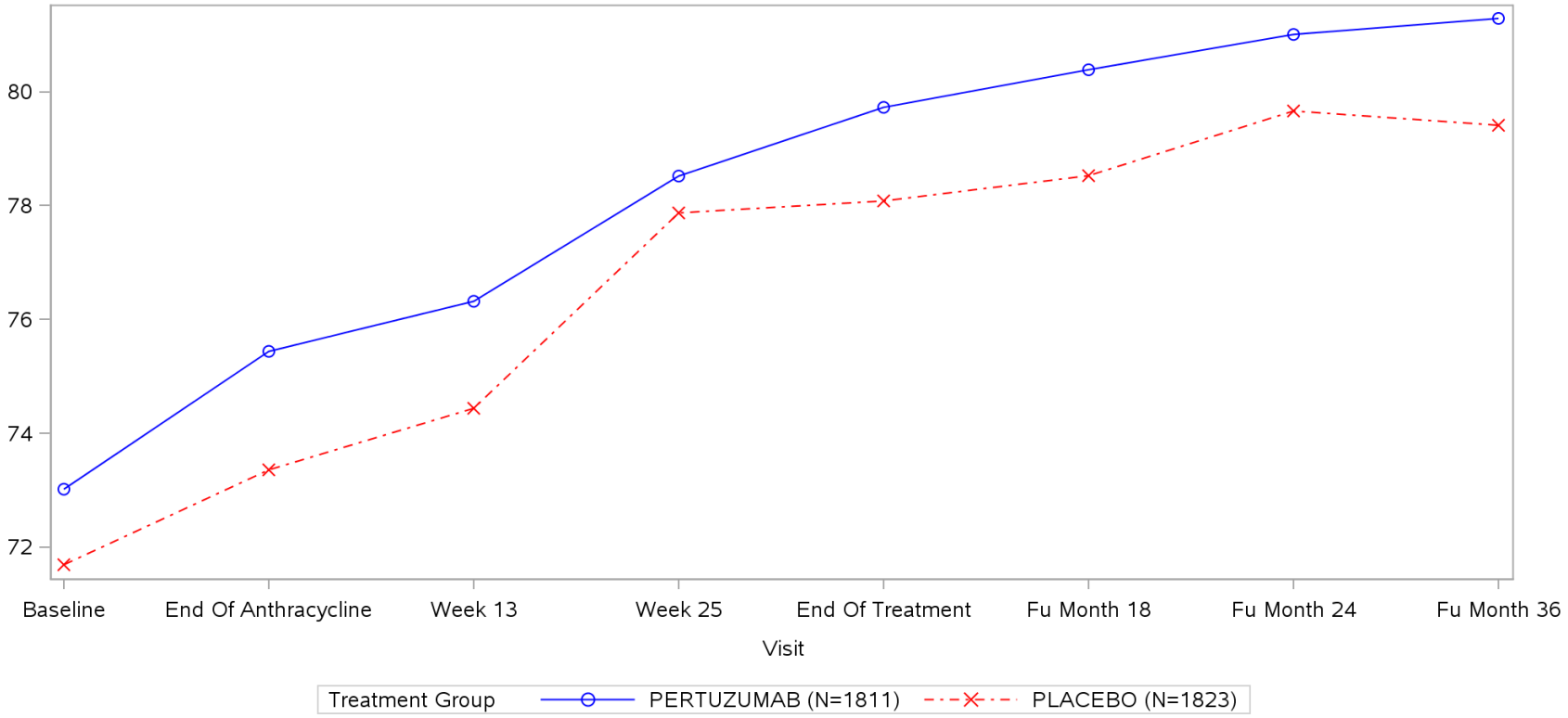
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Role Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC02.pdf
30MAR2020 11:15

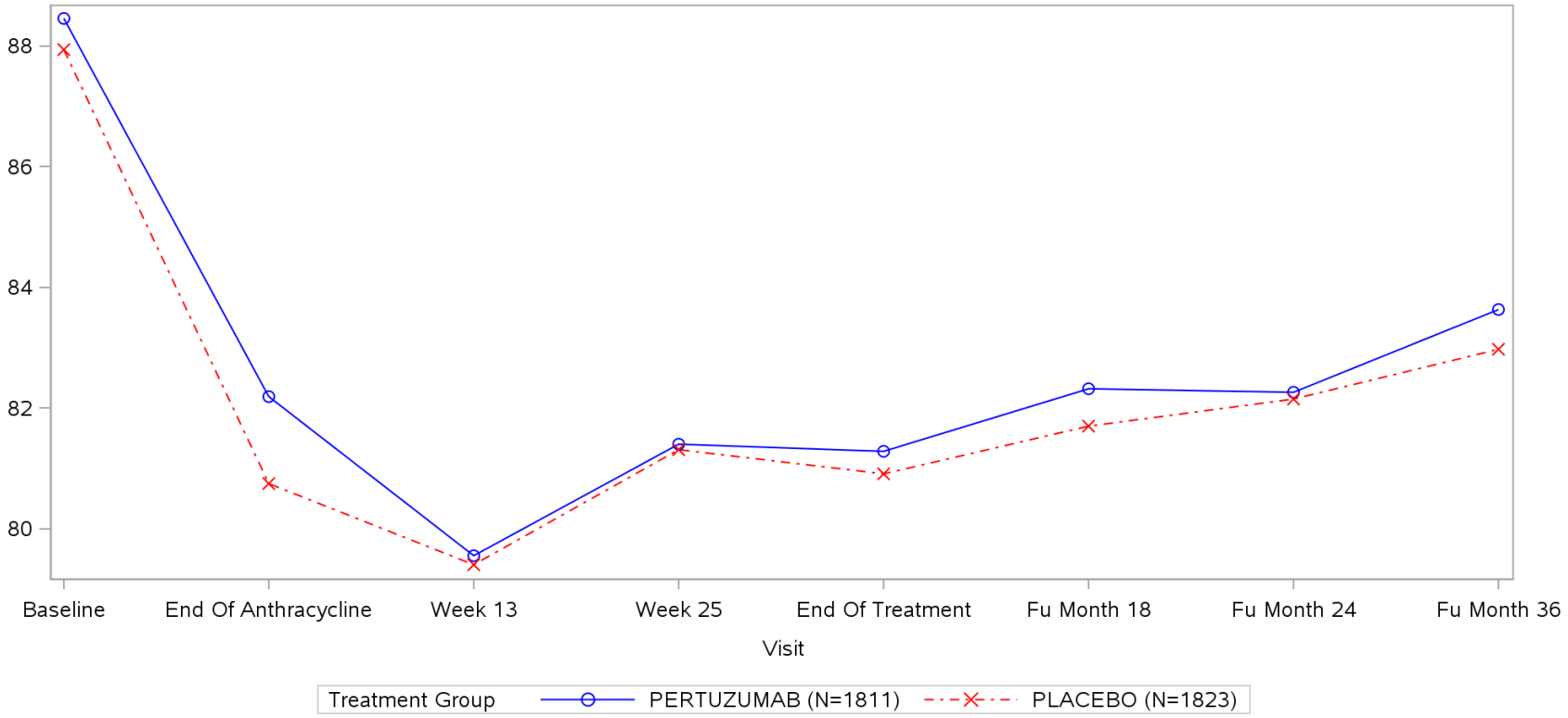
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Emotional Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC03.pdf
30MAR2020 11:16

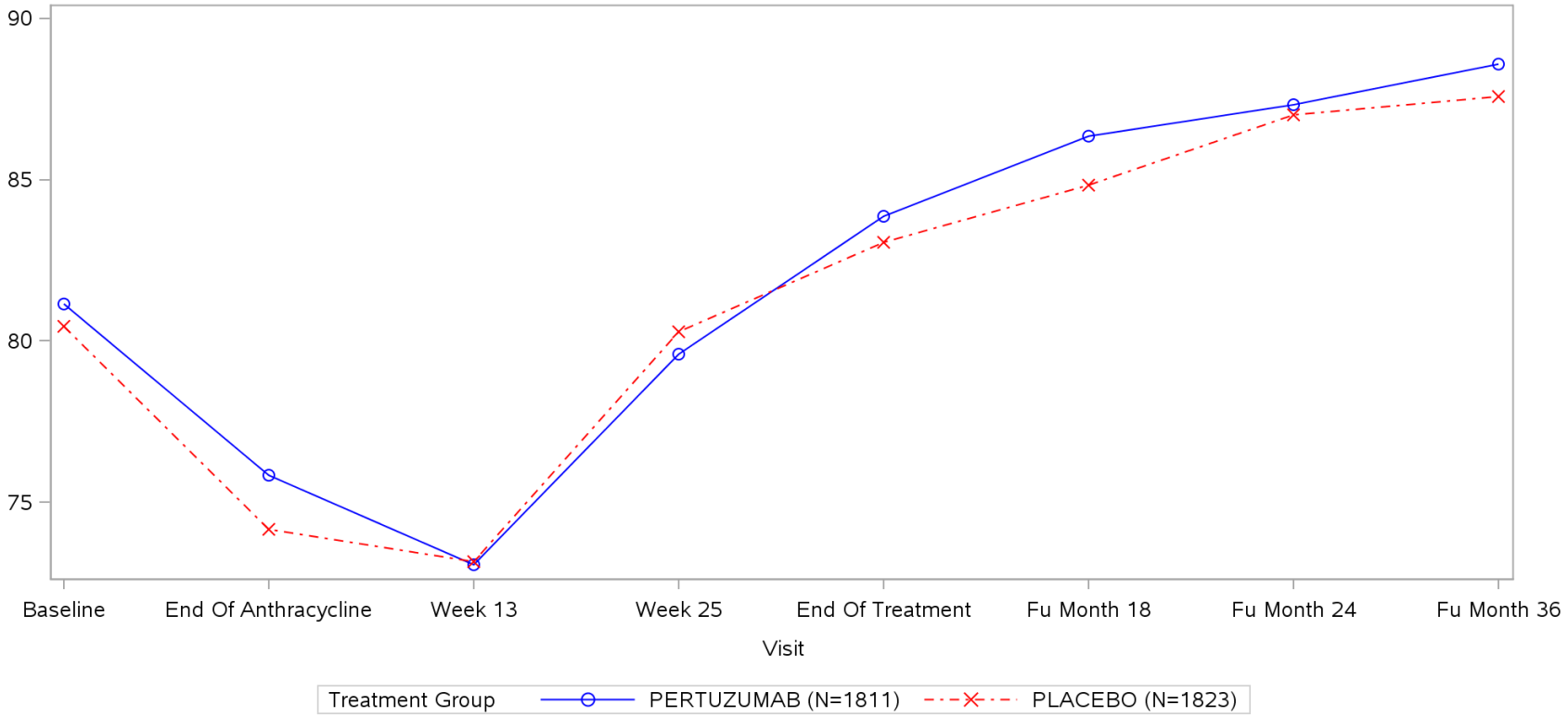
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Cognitive Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC04.pdf
30MAR2020 11:17

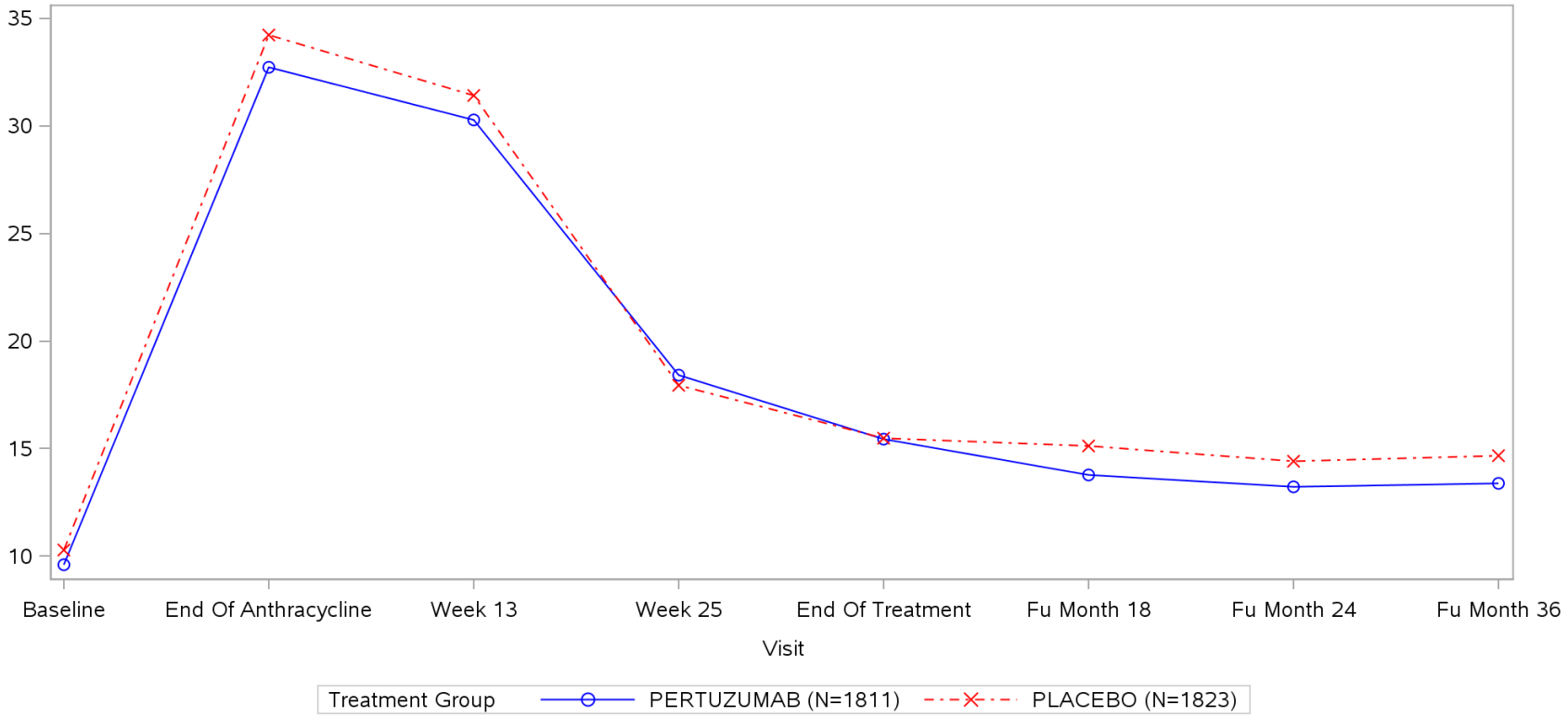
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-C30 Social Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC05.pdf
30MAR2020 11:18

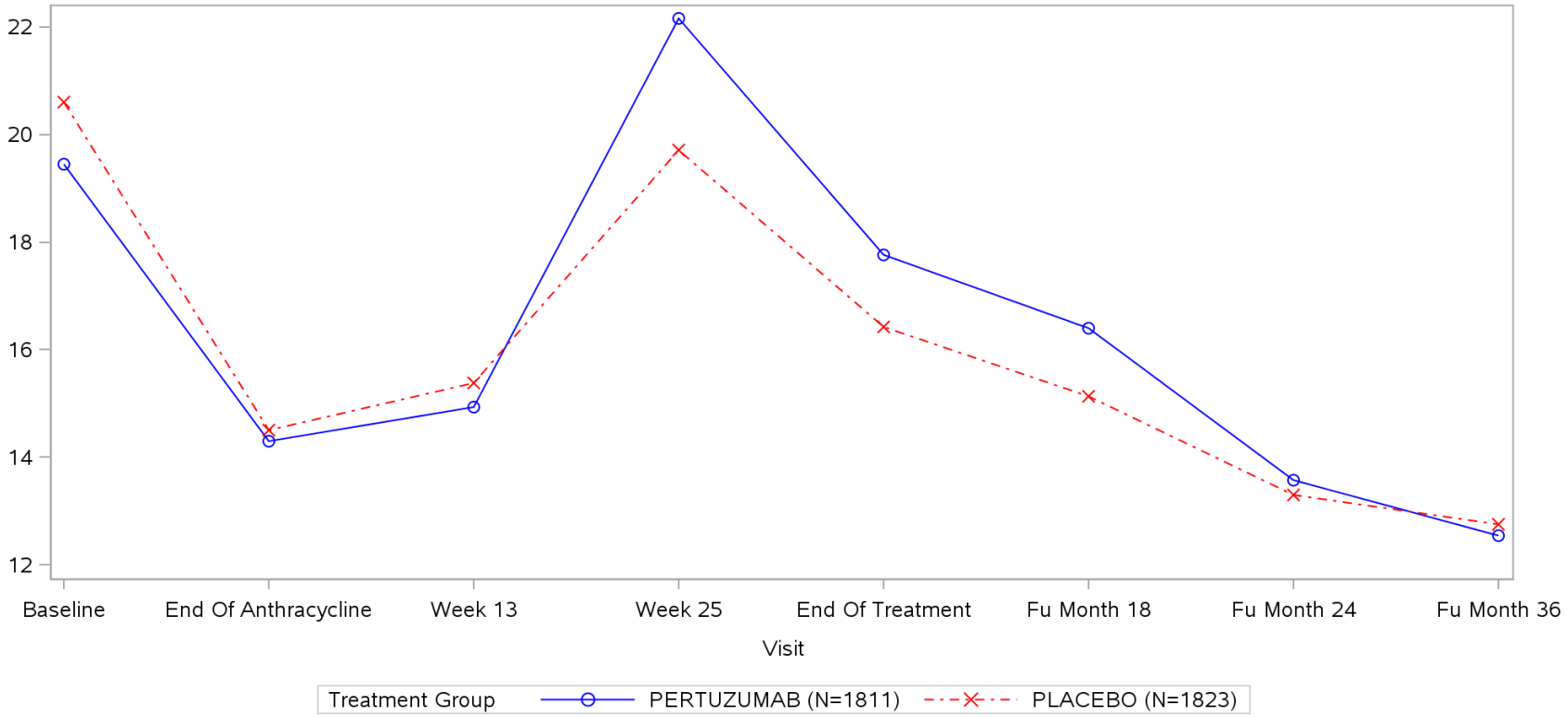
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Systemic Therapy Side Effects Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC10.pdf
30MAR2020 11:28

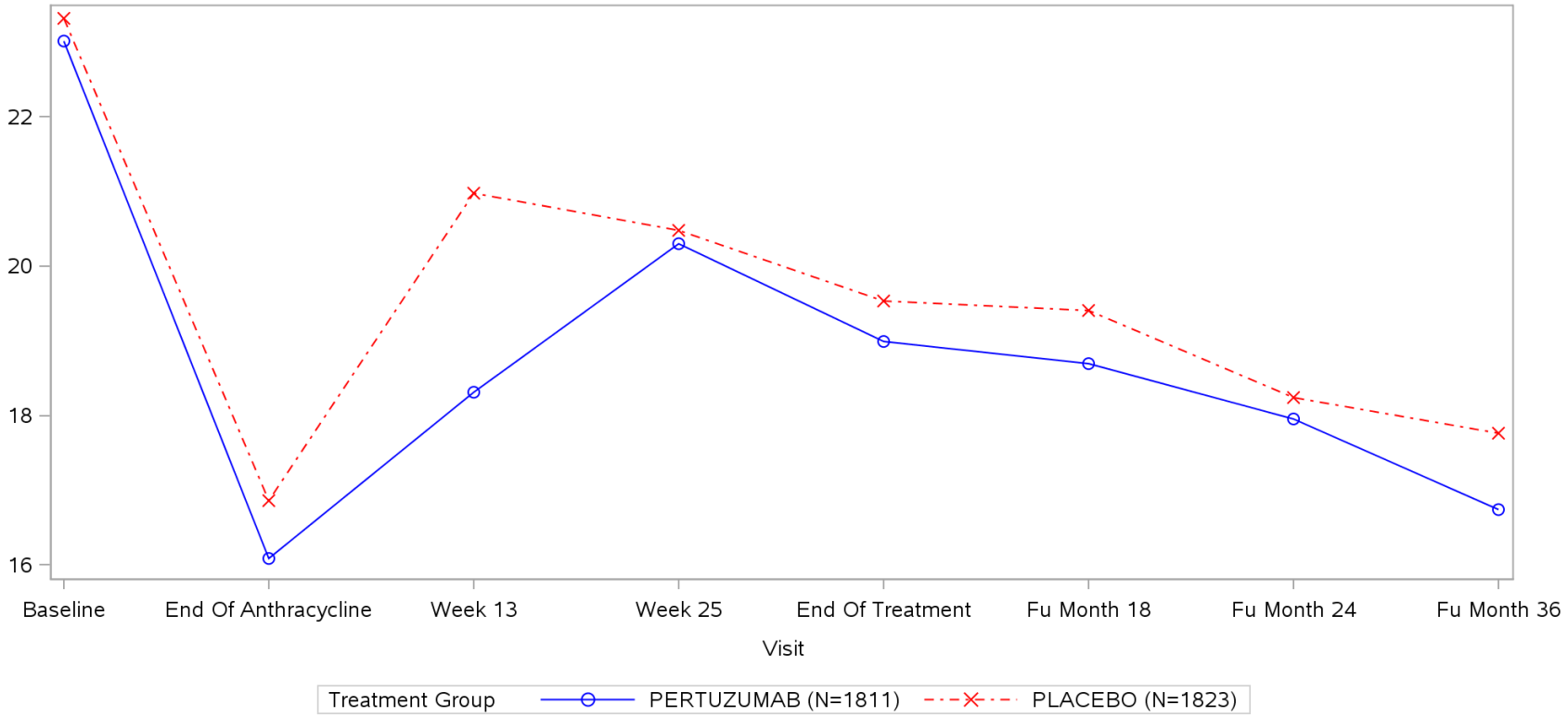
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Breast Symptoms Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC11.pdf
30MAR2020 11:29

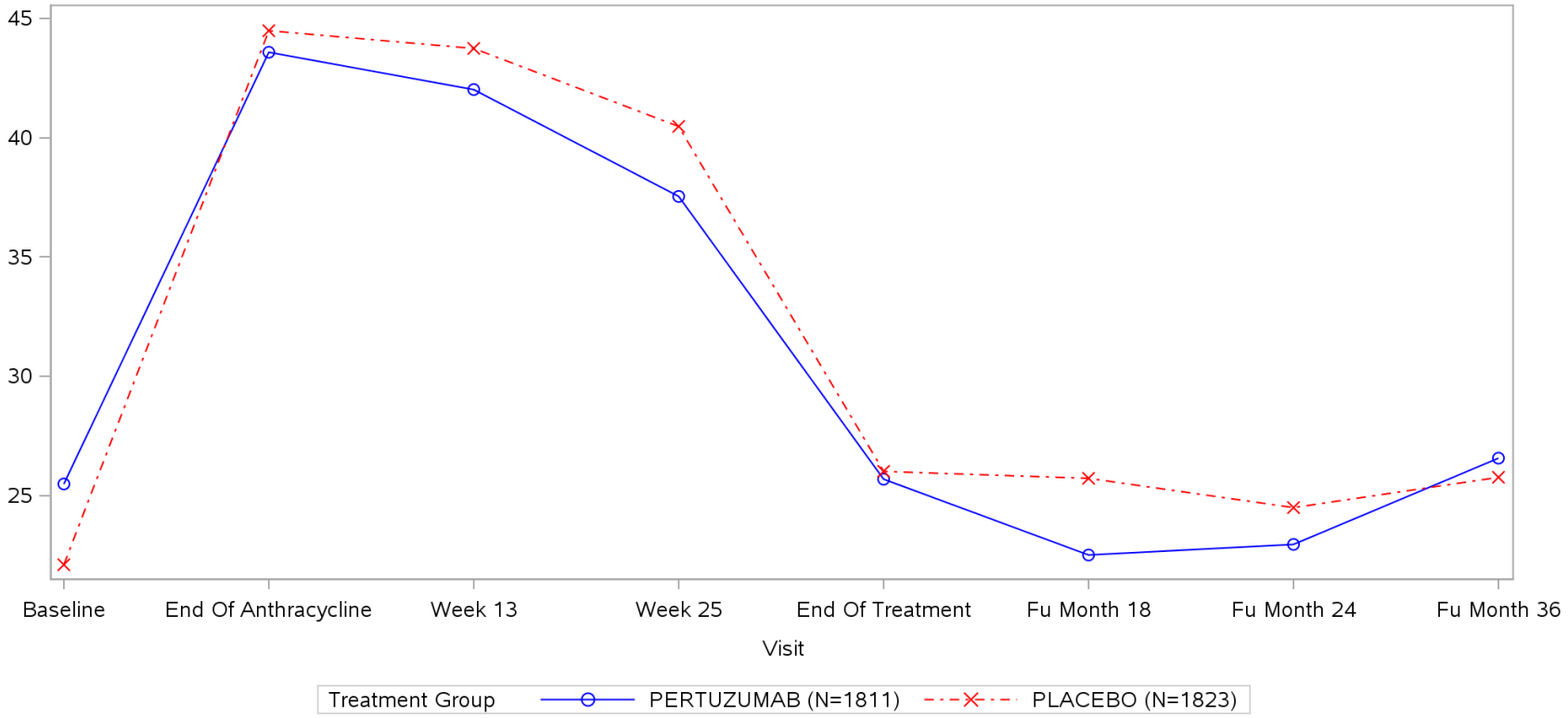
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Arm Symptoms Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC12.pdf
30MAR2020 11:30

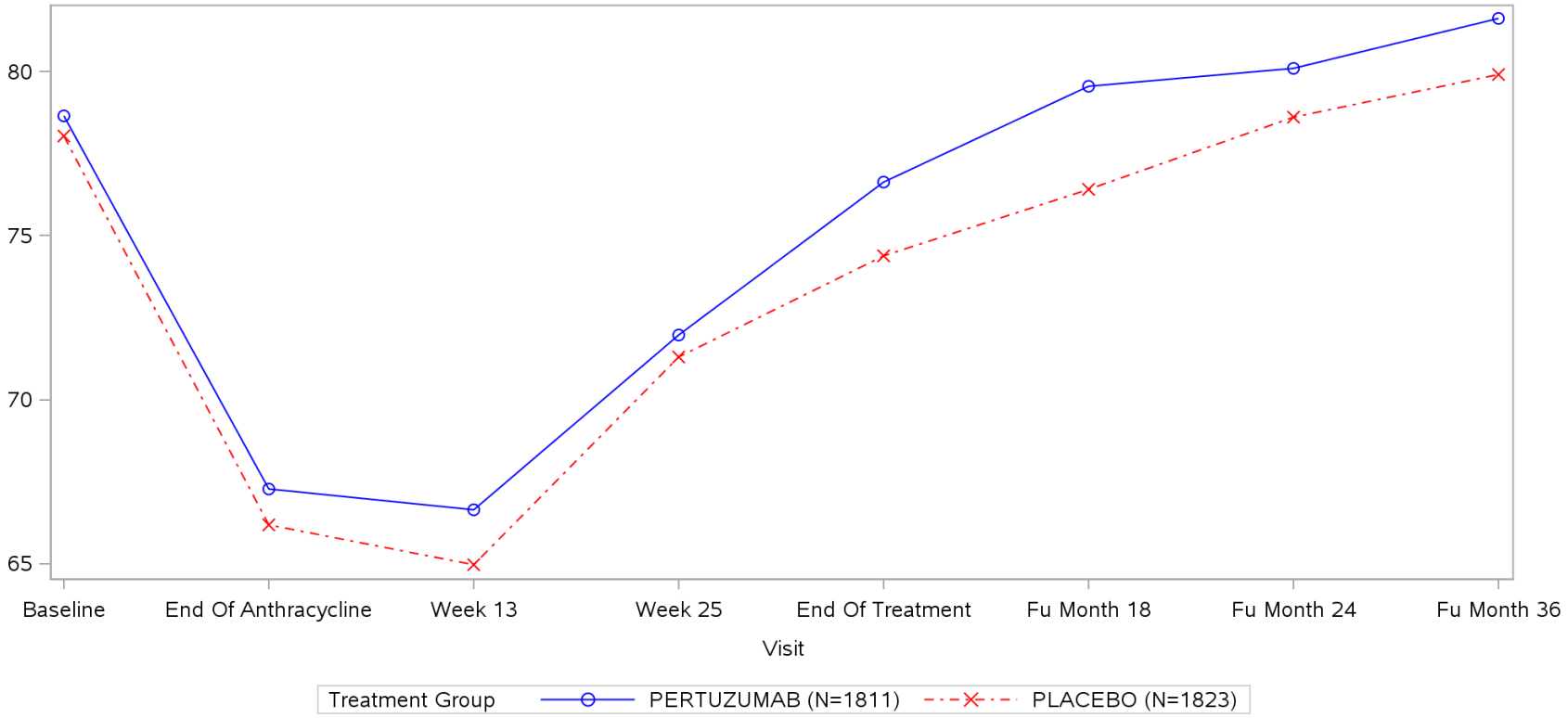
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Upset by Hair Loss Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_SSC13.pdf
30MAR2020 11:31

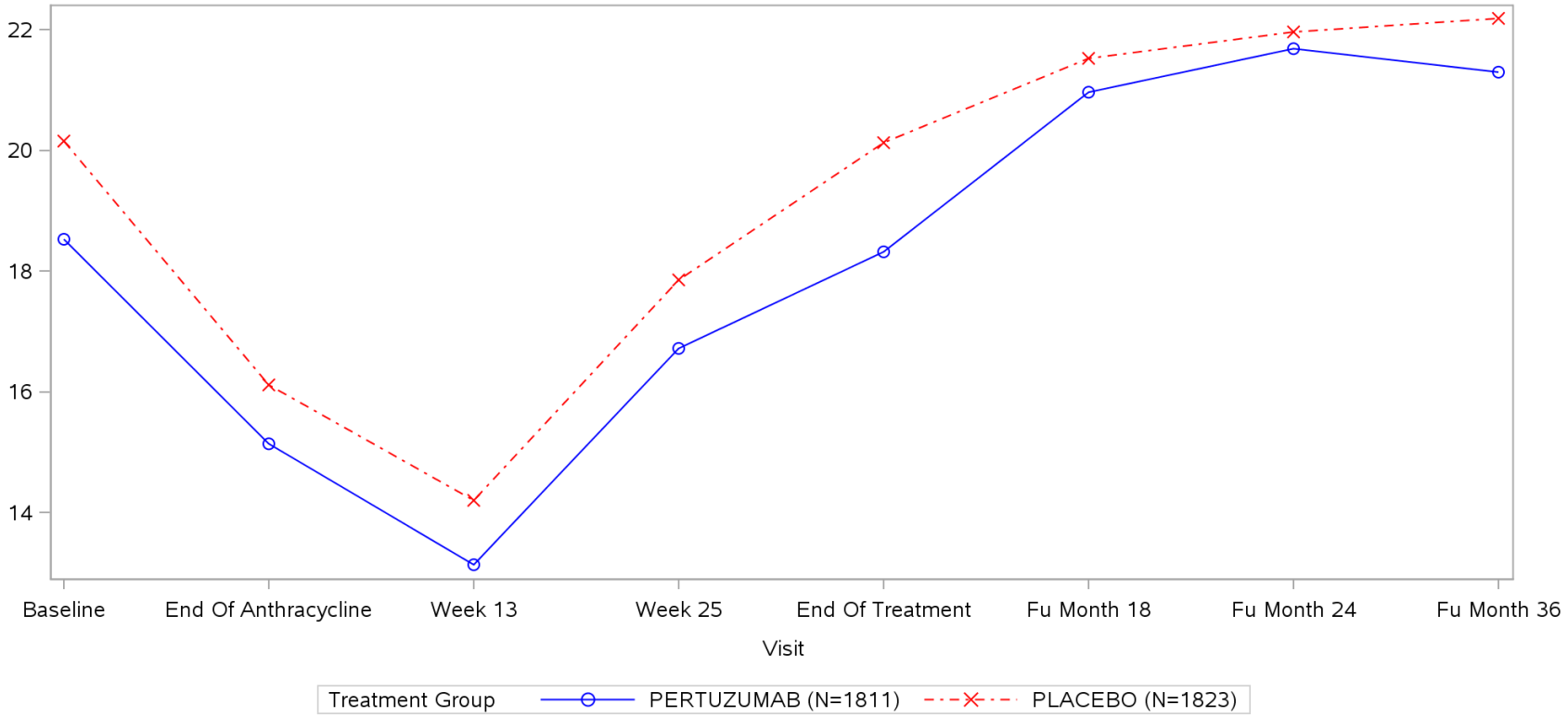
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Body Image Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC06.pdf
30MAR2020 11:18

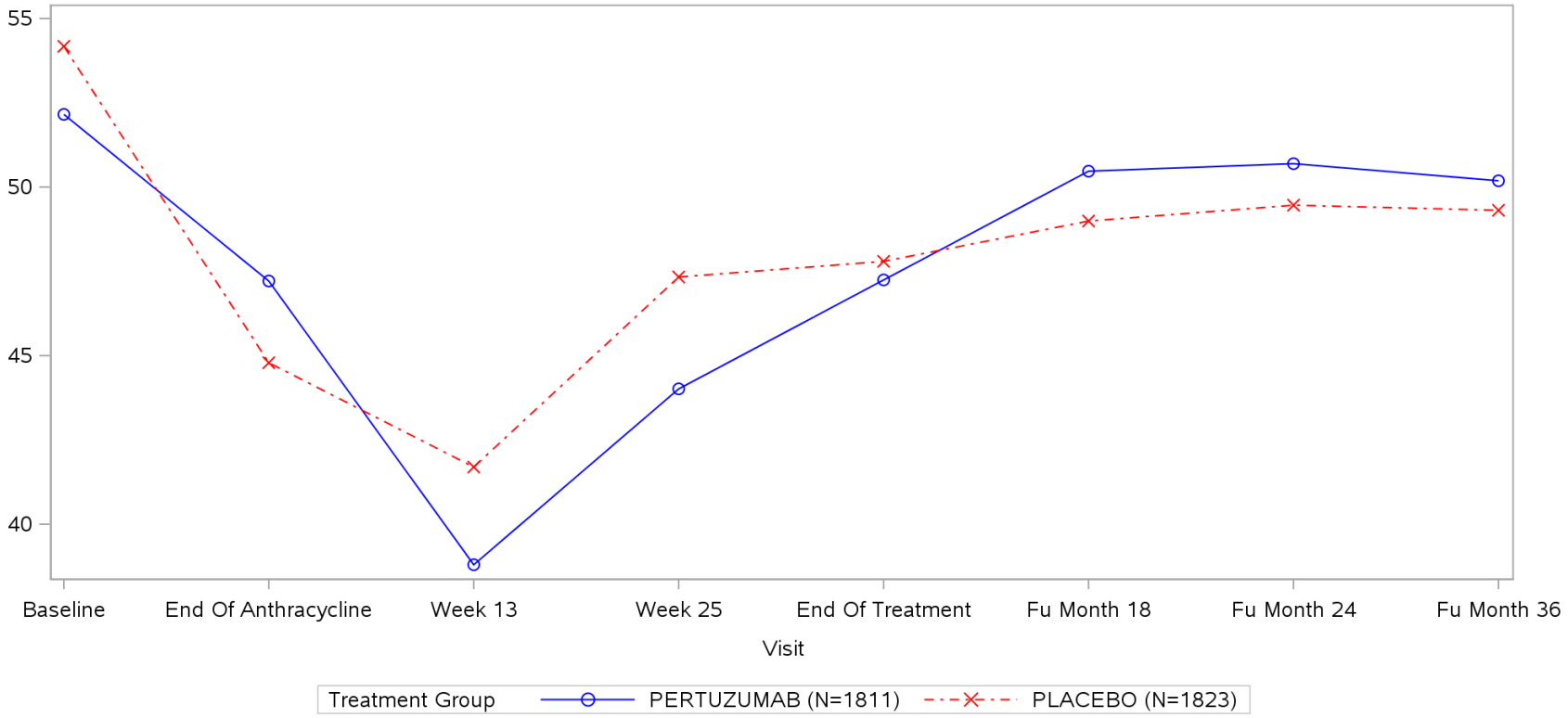
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Functioning Scale
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC07.pdf
30MAR2020 11:19

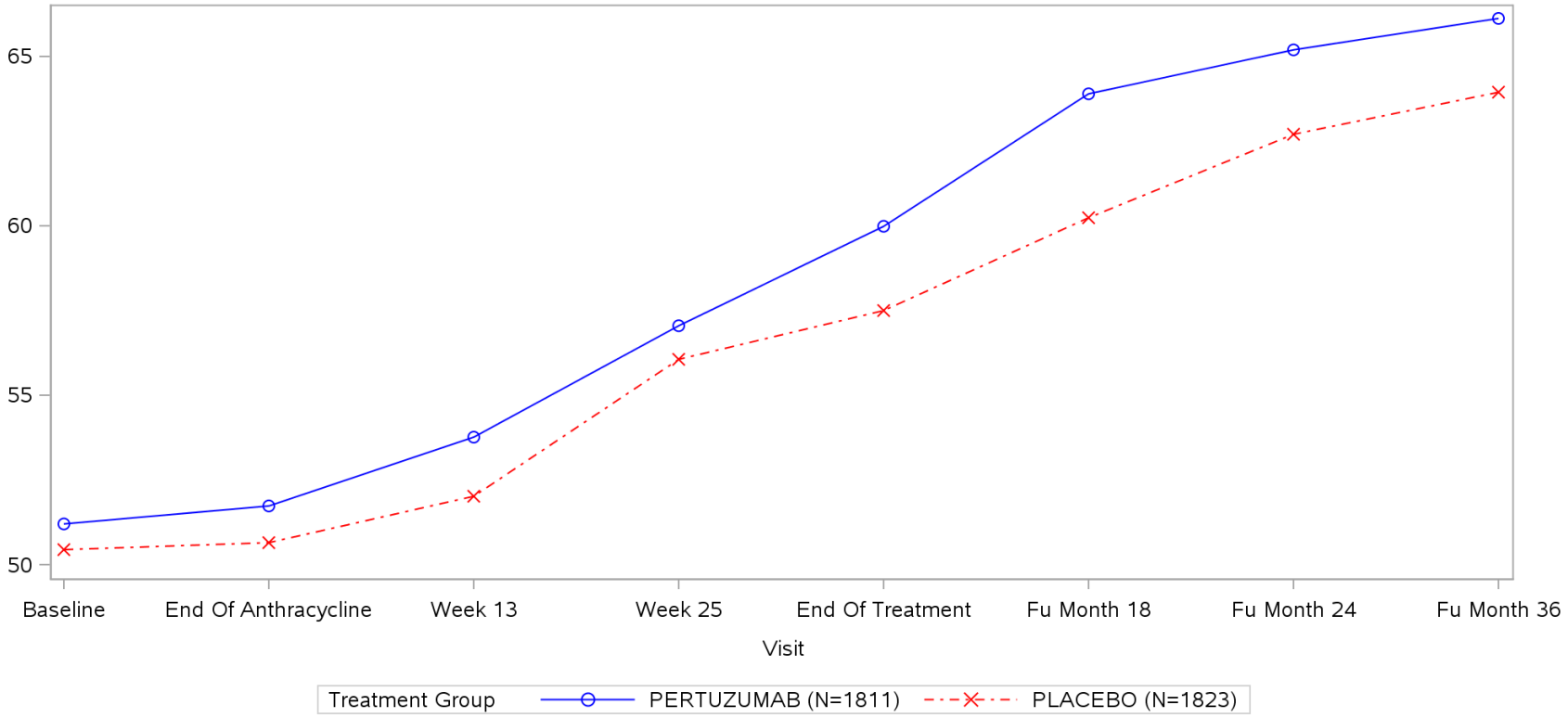
POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Sexual Enjoyment Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC08.pdf
30MAR2020 11:20

POPULATION: HR negative or node positive ITT
ENDPOINT: EORTC QLQ-BR23 Future Perspective Item
MODEL: --
STUDY: BO25126
Plot of mean by visit



Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_26a_19DEC2016_CHON_FSC09.pdf
30MAR2020 11:20

Verträglichkeit (Datenschnitt: 19.12.2016)

Responder Analysen

Generelle Verträglichkeit

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference					Relative Risk							Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
All	n/a	1783	100,0	1782	>99.9	1822	100,0	1811	99,4	10,82	Algorithm converged.	1,40	83,92	0,005	Algorithm converged.	0,002	0,009		1,01	Algorithm converged.	1,00	1,01	0,0040			0,99	Algorithm converged.	0,99	1,00		
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	51	100,0	42	2,3	42	100,0	NE		NE	NE	NE		NE	NE		NE		NE	NE	NE	NE		NE		NE	NE		
	0 positive nodes, tumor > 1 cm	259	14,5	259	100,0	271	14,9	269	99,3	>999	Algorithm converged.	0,00	NE	NE	* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE	* WARNING: Negative of Hessian not positive definite.	NE	NE	NE			NE	* WARNING: Negative of Hessian not positive definite.	NE	NE		
	1-3 positive nodes	891	50,0	891	100,0	905	49,7	899	99,3	>999	Algorithm converged.	0,00	NE	0,029	* WARNING: The relative Hessian convergence criterion of 20.064154109 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,098		NE	* WARNING: Negative of Hessian not positive definite.	NE	NE	NE			NE	* WARNING: Negative of Hessian not positive definite.	NE	NE		
	>= 4 positive nodes	582	32,6	581	99,8	604	33,2	601	99,5	2,90	Algorithm converged.	0,30	27,96	0,003	Algorithm converged.	-0,003	0,010		1,00	Algorithm converged.	1,00	1,01	0,3305			1,00	Algorithm converged.	0,99	1,00		
Geographical region II	USA/Canada	262	14,7	262	100,0	252	13,8	252	100,0	NE		NE	NE	NE		NE	NE		NE		NE	NE	NE	NE		NE		NE	NE		
	Western Europe	814	45,7	814	100,0	824	45,2	818	99,3	>999	Algorithm converged.	0,00	NE	NE	* WARNING: Negative of Hessian not positive definite.	NE	NE		NE	* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			NE	* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		
	Asia Pacific	482	27,0	481	99,8	517	28,4	516	99,8	0,93	Algorithm converged.	0,06	14,94	0,000	Algorithm converged.	-0,006	0,005		1,00	Algorithm converged.	0,99	1,01	0,9602			1,00	Algorithm converged.	0,99	1,01		

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Latin America	42	2,4	42	100,0	45	2,5	42	93,3	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE
	Other	183	10,3	183	100,0	184	10,1	183	99,5	>999		Algorithm converged.	0,00	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 22.853509175 is greater than the limit of 0.0001. The convergence is questionable.	-0,126	0,181	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE
Age II	< 65	1564	87,7	1563	>99.9	1601	87,9	1591	99,4	9,82		Algorithm converged.	1,26	76,83	0,006		Algorithm converged.	0,002	0,010	1,01		Algorithm converged.	1,00	1,01	0,0069	NE	0,99		Algorithm converged.	0,99	1,00
	>= 65	219	12,3	219	100,0	221	12,1	220	99,5	>999		Algorithm converged.	0,00	NE	0,026	*	WARNING: The relative Hessian convergence criterion of 25.362006931 is greater than the limit of 0.0001. The convergence is questionable.	-0,115	0,167	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_ANYAE_S1.xls
09JUN2020 8:50

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	1128	63,3	1822	100,0	1043	57,2	1,29		Algorithm converged.	1,13	1,47	0,060		Algorithm converged.	0,028	0,092	1,11		Algorithm converged.	1,05	1,17	0,0002		0,90		Algorithm converged.	0,86	0,95
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	31	60,8	42	2,3	22	52,4	1,41		Algorithm converged.	0,62	3,22	0,084		Algorithm converged.	-0,118	0,286	1,16		Algorithm converged.	0,81	1,67	0,4217	0,0611	0,86		Algorithm converged.	0,60	1,24
	0 positive nodes, tumor > 1 cm	259	14,5	177	68,3	271	14,9	142	52,4	1,96		Algorithm converged.	1,38	2,79	0,159		Algorithm converged.	0,077	0,242	1,30		Algorithm converged.	1,13	1,50	0,0002		0,77		Algorithm converged.	0,67	0,88
	1-3 positive nodes	891	50,0	564	63,3	905	49,7	545	60,2	1,14		Algorithm converged.	0,94	1,38	0,031		Algorithm converged.	-0,014	0,076	1,05		Algorithm converged.	0,98	1,13	0,1796		0,95		Algorithm converged.	0,88	1,02
	>= 4 positive nodes	582	32,6	356	61,2	604	33,2	334	55,3	1,27		Algorithm converged.	1,01	1,60	0,059		Algorithm converged.	0,003	0,115	1,11		Algorithm converged.	1,00	1,22	0,0407		0,90		Algorithm converged.	0,82	1,00
Geographical region II	USA/Canada	262	14,7	182	69,5	252	13,8	141	56,0	1,79		Algorithm converged.	1,25	2,57	0,135		Algorithm converged.	0,052	0,218	1,24		Algorithm converged.	1,08	1,42	0,0018	0,0085	0,81		Algorithm converged.	0,70	0,92
	Western Europe	814	45,7	510	62,7	824	45,2	513	62,3	1,02		Algorithm converged.	0,83	1,24	0,004		Algorithm converged.	-0,043	0,051	1,01		Algorithm converged.	0,93	1,08	0,8685		0,99		Algorithm converged.	0,92	1,07
	Asia Pacific	482	27,0	336	69,7	517	28,4	300	58,0	1,66		Algorithm converged.	1,28	2,16	0,117		Algorithm converged.	0,058	0,176	1,20		Algorithm converged.	1,09	1,32	0,0001		0,83		Algorithm converged.	0,76	0,91
	Latin America	42	2,4	20	47,6	45	2,5	24	53,3	0,80		Algorithm converged.	0,34	1,85	-0,057		Algorithm converged.	-0,267	0,153	0,89		Algorithm converged.	0,59	1,36	0,5958		1,12		Algorithm converged.	0,74	1,70
	Other	183	10,3	80	43,7	184	10,1	65	35,3	1,42		Algorithm converged.	0,93	2,16	0,084		Algorithm converged.	-0,016	0,184	1,24		Algorithm converged.	0,96	1,60	0,1020		0,81		Algorithm converged.	0,63	1,04
Age II	< 65	1564	87,7	967	61,8	1601	87,9	902	56,3	1,26		Algorithm converged.	1,09	1,45	0,055		Algorithm converged.	0,021	0,089	1,10		Algorithm converged.	1,04	1,16	0,0017	0,4929	0,91		Algorithm converged.	0,86	0,97
	>= 65	219	12,3	161	73,5	221	12,1	141	63,8	1,57		Algorithm converged.	1,05	2,37	0,097		Algorithm converged.	0,011	0,183	1,15		Algorithm converged.	1,01	1,31	0,0290		0,87		Algorithm converged.	0,76	0,99

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AEGR345_S1.xls
09JUN2020 9:06

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	741	41,6	1822	100,0	678	37,2	1,20		Algorithm converged.	1,05	1,37	0,043		Algorithm converged.	0,012	0,075	1,12		Algorithm converged.	1,03	1,21	0,0076		0,90		Algorithm converged.	0,83	0,97
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	17	33,3	42	2,3	14	33,3	1,00		Algorithm converged.	0,42	2,38	0,000		Algorithm converged.	-0,193	0,193	1,00		Algorithm converged.	0,56	1,78	1,0000	0,2299	1,00		Algorithm converged.	0,56	1,78
	0 positive nodes, tumor > 1 cm	259	14,5	113	43,6	271	14,9	89	32,8	1,58		Algorithm converged.	1,11	2,25	0,108		Algorithm converged.	0,026	0,190	1,33		Algorithm converged.	1,07	1,65	0,0112		0,75		Algorithm converged.	0,60	0,94
	1-3 positive nodes	891	50,0	372	41,8	905	49,7	362	40,0	1,08		Algorithm converged.	0,89	1,30	0,018		Algorithm converged.	-0,028	0,063	1,04		Algorithm converged.	0,93	1,17	0,4505		0,96		Algorithm converged.	0,86	1,07
	>= 4 positive nodes	582	32,6	239	41,1	604	33,2	213	35,3	1,28		Algorithm converged.	1,01	1,62	0,058		Algorithm converged.	0,003	0,113	1,16		Algorithm converged.	1,01	1,35	0,0401		0,86		Algorithm converged.	0,74	0,99
Geographical region II	USA/Canada	262	14,7	128	48,9	252	13,8	99	39,3	1,48		Algorithm converged.	1,04	2,10	0,096		Algorithm converged.	0,010	0,181	1,24		Algorithm converged.	1,02	1,51	0,0303	0,0304	0,80		Algorithm converged.	0,66	0,98
	Western Europe	814	45,7	364	44,7	824	45,2	373	45,3	0,98		Algorithm converged.	0,81	1,19	-0,005		Algorithm converged.	-0,054	0,043	0,99		Algorithm converged.	0,89	1,10	0,8231		1,01		Algorithm converged.	0,91	1,13
	Asia Pacific	482	27,0	180	37,3	517	28,4	152	29,4	1,43		Algorithm converged.	1,10	1,86	0,079		Algorithm converged.	0,021	0,138	1,27		Algorithm converged.	1,06	1,52	0,0080		0,79		Algorithm converged.	0,66	0,94
	Latin America	42	2,4	15	35,7	45	2,5	17	37,8	0,92		Algorithm converged.	0,38	2,19	-0,021		Algorithm converged.	-0,223	0,182	0,95		Algorithm converged.	0,54	1,64	0,8421		1,06		Algorithm converged.	0,61	1,84
	Other	183	10,3	54	29,5	184	10,1	37	20,1	1,66		Algorithm converged.	1,03	2,69	0,094		Algorithm converged.	0,006	0,182	1,47		Algorithm converged.	1,02	2,11	0,0394		0,68		Algorithm converged.	0,47	0,98
Age II	< 65	1564	87,7	639	40,9	1601	87,9	591	36,9	1,18		Algorithm converged.	1,02	1,36	0,039		Algorithm converged.	0,005	0,073	1,11		Algorithm converged.	1,01	1,21	0,0230	0,5751	0,90		Algorithm converged.	0,83	0,99
	>= 65	219	12,3	102	46,6	221	12,1	87	39,4	1,34		Algorithm converged.	0,92	1,96	0,072		Algorithm converged.	-0,020	0,164	1,18		Algorithm converged.	0,95	1,47	0,1280		0,85		Algorithm converged.	0,68	1,05

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AEGR3_S1.xls
09JUN2020 9:16

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	378	21,2	1822	100,0	354	19,4	1,12		Algorithm converged.	0,95	1,31	0,018		Algorithm converged.	-0,009	0,044	1,09		Algorithm converged.	0,96	1,24	0,1865		0,92		Algorithm converged.	0,81	1,04
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	12	23,5	42	2,3	8	19,0	1,31		Algorithm converged.	0,48	3,58	0,045		Algorithm converged.	-0,121	0,211	1,24		Algorithm converged.	0,56	2,74	0,6028	0,8156	0,81		Algorithm converged.	0,37	1,79
	0 positive nodes, tumor > 1 cm	259	14,5	63	24,3	271	14,9	53	19,6	1,32		Algorithm converged.	0,87	2,00	0,048		Algorithm converged.	-0,023	0,118	1,24		Algorithm converged.	0,90	1,72	0,1859		0,80		Algorithm converged.	0,58	1,11
	1-3 positive nodes	891	50,0	187	21,0	905	49,7	177	19,6	1,09		Algorithm converged.	0,87	1,38	0,014		Algorithm converged.	-0,023	0,051	1,07		Algorithm converged.	0,89	1,29	0,4512		0,93		Algorithm converged.	0,78	1,12
	>= 4 positive nodes	582	32,6	116	19,9	604	33,2	116	19,2	1,05		Algorithm converged.	0,79	1,40	0,007		Algorithm converged.	-0,038	0,052	1,04		Algorithm converged.	0,82	1,31	0,7527		0,96		Algorithm converged.	0,76	1,21
Geographical region II	USA/Canada	262	14,7	54	20,6	252	13,8	41	16,3	1,34		Algorithm converged.	0,85	2,09	0,043		Algorithm converged.	-0,023	0,110	1,27		Algorithm converged.	0,88	1,83	0,2070	0,7514	0,79		Algorithm converged.	0,55	1,14
	Western Europe	814	45,7	143	17,6	824	45,2	134	16,3	1,10		Algorithm converged.	0,85	1,42	0,013		Algorithm converged.	-0,023	0,049	1,08		Algorithm converged.	0,87	1,34	0,4811		0,93		Algorithm converged.	0,75	1,15
	Asia Pacific	482	27,0	151	31,3	517	28,4	145	28,0	1,17		Algorithm converged.	0,89	1,54	0,033		Algorithm converged.	-0,024	0,090	1,12		Algorithm converged.	0,92	1,35	0,2565		0,90		Algorithm converged.	0,74	1,08
	Latin America	42	2,4	4	9,5	45	2,5	7	15,6	0,57		Algorithm converged.	0,15	2,11	-0,060		Algorithm converged.	-0,199	0,078	0,61		Algorithm converged.	0,19	1,94	0,4048		1,63		Algorithm converged.	0,51	5,18
	Other	183	10,3	26	14,2	184	10,1	27	14,7	0,96		Algorithm converged.	0,54	1,72	-0,005		Algorithm converged.	-0,077	0,067	0,97		Algorithm converged.	0,59	1,59	0,8989		1,03		Algorithm converged.	0,63	1,70
Age II	< 65	1564	87,7	322	20,6	1601	87,9	305	19,1	1,10		Algorithm converged.	0,92	1,31	0,015		Algorithm converged.	-0,012	0,043	1,08		Algorithm converged.	0,94	1,24	0,2780	0,7254	0,93		Algorithm converged.	0,80	1,06
	>= 65	219	12,3	56	25,6	221	12,1	49	22,2	1,21		Algorithm converged.	0,78	1,87	0,034		Algorithm converged.	-0,046	0,114	1,15		Algorithm converged.	0,83	1,61	0,4037		0,87		Algorithm converged.	0,62	1,21

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AEGR4_S1.xls
09JUN2020 9:21

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	9	0,5	1822	100,0	11	0,6	0,84		Algorithm converged.	0,35	2,02	-0,001		Algorithm converged.	-0,006	0,004	0,84		Algorithm converged.	0,35	2,01	0,6896		1,20		Algorithm converged.	0,50	2,88
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133902 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	1-3 positive nodes	891	50,0	5	0,6	905	49,7	6	0,7	0,85		Algorithm converged.	0,26	2,78	-0,001		Algorithm converged.	-0,008	0,006	0,85		Algorithm converged.	0,26	2,76	0,7824		1,18		Algorithm converged.	0,36	3,86
	>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001	0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
	Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
	Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
	Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Age II	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
	>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AEGR5_S1.xls
09JUN2020 9:25

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	508	28,5	1822	100,0	444	24,4	1,24		Algorithm converged.	1,07	1,43	0,041		Algorithm converged.	0,012	0,070	1,17		Algorithm converged.	1,05	1,30	0,0051		0,86		Algorithm converged.	0,77	0,95
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	17	33,3	42	2,3	11	26,2	1,41		Algorithm converged.	0,57	3,47	0,071		Algorithm converged.	-0,114	0,257	1,27		Algorithm converged.	0,67	2,41	0,4595	0,8978	0,79		Algorithm converged.	0,41	1,49
	0 positive nodes, tumor > 1 cm	259	14,5	73	28,2	271	14,9	60	22,1	1,38		Algorithm converged.	0,93	2,05	0,060		Algorithm converged.	-0,013	0,134	1,27		Algorithm converged.	0,95	1,71	0,1100		0,79		Algorithm converged.	0,58	1,06
	1-3 positive nodes	891	50,0	253	28,4	905	49,7	220	24,3	1,23		Algorithm converged.	1,00	1,52	0,041		Algorithm converged.	0,000	0,082	1,17		Algorithm converged.	1,00	1,36	0,0498		0,86		Algorithm converged.	0,73	1,00
	>= 4 positive nodes	582	32,6	165	28,4	604	33,2	153	25,3	1,17		Algorithm converged.	0,90	1,51	0,030		Algorithm converged.	-0,020	0,081	1,12		Algorithm converged.	0,93	1,35	0,2410		0,89		Algorithm converged.	0,74	1,08
Geographical region II	USA/Canada	262	14,7	65	24,8	252	13,8	71	28,2	0,84		Algorithm converged.	0,57	1,25	-0,034		Algorithm converged.	-0,110	0,043	0,88		Algorithm converged.	0,66	1,18	0,3877	0,1035	1,14		Algorithm converged.	0,85	1,52
	Western Europe	814	45,7	261	32,1	824	45,2	226	27,4	1,25		Algorithm converged.	1,01	1,54	0,046		Algorithm converged.	0,002	0,091	1,17		Algorithm converged.	1,01	1,36	0,0405		0,86		Algorithm converged.	0,74	0,99
	Asia Pacific	482	27,0	133	27,6	517	28,4	114	22,1	1,35		Algorithm converged.	1,01	1,80	0,055		Algorithm converged.	0,002	0,109	1,25		Algorithm converged.	1,01	1,55	0,0430		0,80		Algorithm converged.	0,64	0,99
	Latin America	42	2,4	14	33,3	45	2,5	6	13,3	3,25		Algorithm converged.	1,11	9,50	0,200		Algorithm converged.	0,026	0,374	2,50		Algorithm converged.	1,06	5,90	0,0365		0,40		Algorithm converged.	0,17	0,94
	Other	183	10,3	35	19,1	184	10,1	27	14,7	1,38		Algorithm converged.	0,79	2,38	0,045		Algorithm converged.	-0,032	0,121	1,30		Algorithm converged.	0,82	2,06	0,2573		0,77		Algorithm converged.	0,49	1,21
Age II	< 65	1564	87,7	410	26,2	1601	87,9	365	22,8	1,20		Algorithm converged.	1,02	1,42	0,034		Algorithm converged.	0,004	0,064	1,15		Algorithm converged.	1,02	1,30	0,0256	0,5220	0,87		Algorithm converged.	0,77	0,98
	>= 65	219	12,3	98	44,7	221	12,1	79	35,7	1,46		Algorithm converged.	0,99	2,14	0,090		Algorithm converged.	-0,001	0,181	1,25		Algorithm converged.	0,99	1,58	0,0556		0,80		Algorithm converged.	0,63	1,01

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AESAE_S1.xls
09JUN2020 9:28

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference				Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	219	12,3	1822	100,0	219	12,0	1,02		Algorithm converged.	0,84	1,25	0,003		Algorithm converged.	-0,019	0,024	1,02		Algorithm converged.	0,86	1,22	0,8091		0,98		Algorithm converged.	0,82	1,17
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,2445	0,81		Algorithm converged.	0,24	2,68
	0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	42	15,5	0,66		Algorithm converged.	0,40	1,10	-0,047		Algorithm converged.	-0,104	0,010	0,70		Algorithm converged.	0,45	1,09	0,1141		1,43		Algorithm converged.	0,92	2,24
	1-3 positive nodes	891	50,0	110	12,3	905	49,7	109	12,0	1,03		Algorithm converged.	0,78	1,36	0,003		Algorithm converged.	-0,027	0,033	1,03		Algorithm converged.	0,80	1,31	0,8452		0,98		Algorithm converged.	0,76	1,25
	>= 4 positive nodes	582	32,6	75	12,9	604	33,2	64	10,6	1,25		Algorithm converged.	0,88	1,78	0,023		Algorithm converged.	-0,014	0,060	1,22		Algorithm converged.	0,89	1,66	0,2211		0,82		Algorithm converged.	0,60	1,13
Geographical region II	USA/Canada	262	14,7	41	15,6	252	13,8	30	11,9	1,37		Algorithm converged.	0,83	2,28	0,037		Algorithm converged.	-0,022	0,097	1,31		Algorithm converged.	0,85	2,04	0,2211	-	0,76		Algorithm converged.	0,49	1,18
	Western Europe	814	45,7	118	14,5	824	45,2	125	15,2	0,95		Algorithm converged.	0,72	1,25	-0,007		Algorithm converged.	-0,041	0,028	0,96		Algorithm converged.	0,76	1,21	0,7014		1,05		Algorithm converged.	0,83	1,32
	Asia Pacific	482	27,0	36	7,5	517	28,4	41	7,9	0,94		Algorithm converged.	0,59	1,49	-0,005		Algorithm converged.	-0,038	0,028	0,94		Algorithm converged.	0,61	1,45	0,7847		1,06		Algorithm converged.	0,69	1,63
	Latin America	42	2,4	5	11,9	45	2,5	4	8,9	1,39		Algorithm converged.	0,35	5,55	0,030		Algorithm converged.	-0,098	0,159	1,34		Algorithm converged.	0,39	4,65	0,6458		0,75		Algorithm converged.	0,21	2,60
	Other	183	10,3	19	10,4	184	10,1	19	10,3	1,01		Algorithm converged.	0,51	1,97	0,001		Algorithm converged.	-0,062	0,063	1,01		Algorithm converged.	0,55	1,84	0,9858		0,99		Algorithm converged.	0,54	1,82
Age II	< 65	1564	87,7	161	10,3	1601	87,9	163	10,2	1,01		Algorithm converged.	0,80	1,27	0,001		Algorithm converged.	-0,020	0,022	1,01		Algorithm converged.	0,82	1,24	0,9165	0,8633	0,99		Algorithm converged.	0,80	1,22
	>= 65	219	12,3	58	26,5	221	12,1	56	25,3	1,06		Algorithm converged.	0,69	1,63	0,011		Algorithm converged.	-0,070	0,093	1,05		Algorithm converged.	0,76	1,43	0,7841		0,96		Algorithm converged.	0,70	1,31

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/saf_raw_26a_19DEC2016_CHNS_AEDISC_S1.xls
09JUN2020 9:32

Verträglichkeit (Datenschnitt: 19.06.2019)

Responder Analysen

Generelle Verträglichkeit

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk										Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	1783	100,0	1782	>99.9	1822	100,0	1813	99,5	8,85		Algorithm converged.	1,12	69,90	0,004		Algorithm converged.	0,001	0,008		1,004	*	WARNING: The relative Hessian convergence criterion of 0.0001383416 is greater than the limit of 0.0001. The convergence is questionable.	1,001	1,008	0,0101			0,996	*	WARNING: The relative Hessian convergence criterion of 0.0001383416 is greater than the limit of 0.0001. The convergence is questionable.	0,992	0,999
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	51	100,0	42	2,3	42	100,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	0 positive nodes, tumor > 1 cm	259	14,5	259	100,0	271	14,9	269	99,3	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	1-3 positive nodes	891	50,0	891	100,0	905	49,7	900	99,4	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	>= 4 positive nodes	582	32,6	581	99,8	604	33,2	602	99,7	1,93		Algorithm converged.	0,17	21,34	0,002		Algorithm converged.	-0,004	0,007	1,002		Algorithm converged.	0,996	1,007	0,5829		0,998		Algorithm converged.	0,993	1,004
Geographical region II	USA/Canada	262	14,7	262	100,0	252	13,8	252	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE	NE			NE	NE
	Western Europe	814	45,7	814	100,0	824	45,2	819	99,4	>999		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Asia Pacific	482	27,0	481	99,8	517	28,4	516	99,8	0,93		Algorithm converged.	0,06	14,94	0,000		Algorithm converged.	-0,006	0,005	1,000		Algorithm converged.	0,994	1,005	0,9602		1,000		Algorithm converged.	0,995	1,006
	Latin America	42	2,4	42	100,0	45	2,5	42	93,3	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE
	Other	183	10,3	183	100,0	184	10,1	184	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE		NE			NE	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL			Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Age II	< 65	1564	87,7	1563	>99.9	1601	87,9	1593	99,5	7,85		Algorithm converged.	0,98	62,83	0,004		Algorithm converged.	0,001	0,008			1,004		Algorithm converged.	1,001	1,008	0,0203	NE	0,996		Algorithm converged.	0,992	0,999
	>= 65	219	12,3	219	100,0	221	12,1	220	99,5	>999		Algorithm converged.	0,00	NE	0,026	*	WARNING: The relative Hessian convergence criterion of 25.362006931 is greater than the limit of 0.0001. The convergence is questionable.	-0,115	0,167			NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_ANYAE_S1.xls
13AUG2020 15:01

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk										Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	1141	64,0	1822	100,0	1055	57,9	1,29		Algorithm converged.	1,13	1,48	0,061		Algorithm converged.	0,029	0,093	1,11		Algorithm converged.	1,05	1,16	0,0002		0,90		Algorithm converged.	0,86	0,95
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	32	62,7	42	2,3	22	52,4	1,53		Algorithm converged.	0,67	3,51	0,104		Algorithm converged.	-0,097	0,305	1,20		Algorithm converged.	0,84	1,71	0,3224	0,0589	0,83		Algorithm converged.	0,58	1,19
	0 positive nodes, tumor > 1 cm	259	14,5	177	68,3	271	14,9	143	52,8	1,93		Algorithm converged.	1,36	2,75	0,156		Algorithm converged.	0,074	0,238	1,30		Algorithm converged.	1,13	1,49	0,0003		0,77		Algorithm converged.	0,67	0,89
	1-3 positive nodes	891	50,0	568	63,7	905	49,7	551	60,9	1,13		Algorithm converged.	0,93	1,37	0,029		Algorithm converged.	-0,016	0,073	1,05		Algorithm converged.	0,97	1,13	0,2105		0,96		Algorithm converged.	0,89	1,03
	>= 4 positive nodes	582	32,6	364	62,5	604	33,2	339	56,1	1,31		Algorithm converged.	1,03	1,65	0,064		Algorithm converged.	0,008	0,120	1,11		Algorithm converged.	1,01	1,22	0,0247		0,90		Algorithm converged.	0,82	0,99
Geographical region II	USA/Canada	262	14,7	182	69,5	252	13,8	141	56,0	1,79		Algorithm converged.	1,25	2,57	0,135		Algorithm converged.	0,052	0,218	1,24		Algorithm converged.	1,08	1,42	0,0018	0,0089	0,81		Algorithm converged.	0,70	0,92
	Western Europe	814	45,7	517	63,5	824	45,2	519	63,0	1,02		Algorithm converged.	0,84	1,25	0,005		Algorithm converged.	-0,041	0,052	1,01		Algorithm converged.	0,94	1,09	0,8246		0,99		Algorithm converged.	0,92	1,07
	Asia Pacific	482	27,0	340	70,5	517	28,4	305	59,0	1,66		Algorithm converged.	1,28	2,16	0,115		Algorithm converged.	0,057	0,174	1,20		Algorithm converged.	1,09	1,31	0,0001		0,84		Algorithm converged.	0,76	0,92
	Latin America	42	2,4	20	47,6	45	2,5	24	53,3	0,80		Algorithm converged.	0,34	1,85	-0,057		Algorithm converged.	-0,267	0,153	0,89		Algorithm converged.	0,59	1,36	0,5958		1,12		Algorithm converged.	0,74	1,70
	Other	183	10,3	82	44,8	184	10,1	66	35,9	1,45		Algorithm converged.	0,95	2,21	0,089		Algorithm converged.	-0,011	0,189	1,25		Algorithm converged.	0,97	1,61	0,0827		0,80		Algorithm converged.	0,62	1,03
Age II	< 65	1564	87,7	978	62,5	1601	87,9	914	57,1	1,25		Algorithm converged.	1,09	1,45	0,054		Algorithm converged.	0,020	0,089	1,10		Algorithm converged.	1,03	1,16	0,0018	0,3701	0,91		Algorithm converged.	0,86	0,97

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	163	74,4	221	12,1	141	63,8	1,65		Algorithm converged.	1,10	2,49	0,106		Algorithm converged.	0,021	0,192	1,17		Algorithm converged.	1,03	1,32	0,0166		0,86		Algorithm converged.	0,76	0,97

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AEGR345_S1.xls
10JUN2020 11:28

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	751	42,1	1822	100,0	682	37,4	1,22		Algorithm converged.	1,06	1,39	0,047		Algorithm converged.	0,015	0,079	1,13		Algorithm converged.	1,04	1,22	0,0041		0,89		Algorithm converged.	0,82	0,96
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	18	35,3	42	2,3	14	33,3	1,09		Algorithm converged.	0,46	2,58	0,020		Algorithm converged.	-0,174	0,213	1,06		Algorithm converged.	0,60	1,87	0,8433	0,2030	0,94		Algorithm converged.	0,54	1,66
	0 positive nodes, tumor > 1 cm	259	14,5	113	43,6	271	14,9	89	32,8	1,58		Algorithm converged.	1,11	2,25	0,108		Algorithm converged.	0,026	0,190	1,33		Algorithm converged.	1,07	1,65	0,0112		0,75		Algorithm converged.	0,60	0,94
	1-3 positive nodes	891	50,0	375	42,1	905	49,7	365	40,3	1,08		Algorithm converged.	0,89	1,30	0,018		Algorithm converged.	-0,028	0,063	1,04		Algorithm converged.	0,93	1,17	0,4497		0,96		Algorithm converged.	0,86	1,07
	>= 4 positive nodes	582	32,6	245	42,1	604	33,2	214	35,4	1,32		Algorithm converged.	1,05	1,67	0,067		Algorithm converged.	0,011	0,122	1,19		Algorithm converged.	1,03	1,37	0,0188		0,84		Algorithm converged.	0,73	0,97
Geographical region II	USA/Canada	262	14,7	128	48,9	252	13,8	99	39,3	1,48		Algorithm converged.	1,04	2,10	0,096		Algorithm converged.	0,010	0,181	1,24		Algorithm converged.	1,02	1,51	0,0303	0,0196	0,80		Algorithm converged.	0,66	0,98
	Western Europe	814	45,7	369	45,3	824	45,2	377	45,8	0,98		Algorithm converged.	0,81	1,19	-0,004		Algorithm converged.	-0,052	0,044	0,99		Algorithm converged.	0,89	1,10	0,8643		1,01		Algorithm converged.	0,91	1,12
	Asia Pacific	482	27,0	183	38,0	517	28,4	151	29,2	1,48		Algorithm converged.	1,14	1,93	0,088		Algorithm converged.	0,029	0,146	1,30		Algorithm converged.	1,09	1,55	0,0035		0,77		Algorithm converged.	0,65	0,92
	Latin America	42	2,4	15	35,7	45	2,5	17	37,8	0,92		Algorithm converged.	0,38	2,19	-0,021		Algorithm converged.	-0,223	0,182	0,95		Algorithm converged.	0,54	1,64	0,8421		1,06		Algorithm converged.	0,61	1,84
	Other	183	10,3	56	30,6	184	10,1	38	20,7	1,69		Algorithm converged.	1,05	2,73	0,099		Algorithm converged.	0,011	0,188	1,48		Algorithm converged.	1,04	2,12	0,0311		0,67		Algorithm converged.	0,47	0,96
Age II	< 65	1564	87,7	647	41,4	1601	87,9	597	37,3	1,19		Algorithm converged.	1,03	1,37	0,041		Algorithm converged.	0,007	0,075	1,11		Algorithm converged.	1,02	1,21	0,0189	0,3683	0,90		Algorithm converged.	0,83	0,98

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	104	47,5	221	12,1	85	38,5	1,45		Algorithm converged.	0,99	2,11	0,090		Algorithm converged.	-0,002	0,182	1,23		Algorithm converged.	0,99	1,53	0,0572		0,81		Algorithm converged.	0,65	1,01

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AEGR3_S1.xls
10JUN2020 11:32

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	381	21,4	1822	100,0	362	19,9	1,10		Algorithm converged.	0,93	1,29	0,015		Algorithm converged.	-0,011	0,041	1,08		Algorithm converged.	0,95	1,22	0,2657		0,93		Algorithm converged.	0,82	1,06
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	12	23,5	42	2,3	8	19,0	1,31		Algorithm converged.	0,48	3,58	0,045		Algorithm converged.	-0,121	0,211	1,24		Algorithm converged.	0,56	2,74	0,6028	0,8146	0,81		Algorithm converged.	0,37	1,79
	0 positive nodes, tumor > 1 cm	259	14,5	63	24,3	271	14,9	54	19,9	1,29		Algorithm converged.	0,86	1,95	0,044		Algorithm converged.	-0,027	0,115	1,22		Algorithm converged.	0,89	1,68	0,2235		0,82		Algorithm converged.	0,59	1,13
	1-3 positive nodes	891	50,0	188	21,1	905	49,7	180	19,9	1,08		Algorithm converged.	0,86	1,35	0,012		Algorithm converged.	-0,025	0,049	1,06		Algorithm converged.	0,88	1,27	0,5252		0,94		Algorithm converged.	0,79	1,13
	>= 4 positive nodes	582	32,6	118	20,3	604	33,2	120	19,9	1,03		Algorithm converged.	0,77	1,36	0,004		Algorithm converged.	-0,042	0,050	1,02		Algorithm converged.	0,81	1,28	0,8610		0,98		Algorithm converged.	0,78	1,23
Geographical region II	USA/Canada	262	14,7	54	20,6	252	13,8	41	16,3	1,34		Algorithm converged.	0,85	2,09	0,043		Algorithm converged.	-0,023	0,110	1,27		Algorithm converged.	0,88	1,83	0,2070	0,7567	0,79		Algorithm converged.	0,55	1,14
	Western Europe	814	45,7	145	17,8	824	45,2	136	16,5	1,10		Algorithm converged.	0,85	1,42	0,013		Algorithm converged.	-0,023	0,050	1,08		Algorithm converged.	0,87	1,34	0,4826		0,93		Algorithm converged.	0,75	1,15
	Asia Pacific	482	27,0	152	31,5	517	28,4	151	29,2	1,12		Algorithm converged.	0,85	1,46	0,023		Algorithm converged.	-0,034	0,080	1,08		Algorithm converged.	0,89	1,30	0,4237		0,93		Algorithm converged.	0,77	1,12
	Latin America	42	2,4	4	9,5	45	2,5	7	15,6	0,57		Algorithm converged.	0,15	2,11	-0,060		Algorithm converged.	-0,199	0,078	0,61		Algorithm converged.	0,19	1,94	0,4048		1,63		Algorithm converged.	0,51	5,18
	Other	183	10,3	26	14,2	184	10,1	27	14,7	0,96		Algorithm converged.	0,54	1,72	-0,005		Algorithm converged.	-0,077	0,067	0,97		Algorithm converged.	0,59	1,59	0,8989		1,03		Algorithm converged.	0,63	1,70
Age II	< 65	1564	87,7	325	20,8	1601	87,9	311	19,4	1,09		Algorithm converged.	0,91	1,29	0,014		Algorithm converged.	-0,014	0,041	1,07		Algorithm converged.	0,93	1,23	0,3418	0,8472	0,93		Algorithm converged.	0,81	1,07

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	56	25,6	221	12,1	51	23,1	1,15		Algorithm converged.	0,74	1,77	0,025		Algorithm converged.	−0,055	0,105	1,11		Algorithm converged.	0,80	1,54	0,5424		0,90		Algorithm converged.	0,65	1,26

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AEGR4_S1.xls
10JUN2020 11:37

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	9	0,5	1822	100,0	11	0,6	0,84		Algorithm converged.	0,35	2,02	-0,001		Algorithm converged.	-0,006	0,004	0,84		Algorithm converged.	0,35	2,01	0,6896		1,20		Algorithm converged.	0,50	2,88
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133902 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	1-3 positive nodes	891	50,0	5	0,6	905	49,7	6	0,7	0,85		Algorithm converged.	0,26	2,78	-0,001		Algorithm converged.	-0,008	0,006	0,85		Algorithm converged.	0,26	2,76	0,7824		1,18		Algorithm converged.	0,36	3,86
	>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001	0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL			Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE			0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
	Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004			0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
	Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016			1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
	Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE			0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Age II	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
	>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AEGR5_S1.xls
10JUN2020 11:41

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk									Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	509	28,5	1822	100,0	446	24,5	1,23		Algorithm converged.	1,06	1,43	0,041		Algorithm converged.	0,012	0,069	1,17		Algorithm converged.	1,05	1,30	0,0057		0,86		Algorithm converged.	0,77	0,96
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	17	33,3	42	2,3	11	26,2	1,41		Algorithm converged.	0,57	3,47	0,071		Algorithm converged.	-0,114	0,257	1,27		Algorithm converged.	0,67	2,41	0,4595	0,8815	0,79		Algorithm converged.	0,41	1,49
	0 positive nodes, tumor > 1 cm	259	14,5	73	28,2	271	14,9	60	22,1	1,38		Algorithm converged.	0,93	2,05	0,060		Algorithm converged.	-0,013	0,134	1,27		Algorithm converged.	0,95	1,71	0,1100		0,79		Algorithm converged.	0,58	1,06
	1-3 positive nodes	891	50,0	253	28,4	905	49,7	220	24,3	1,23		Algorithm converged.	1,00	1,52	0,041		Algorithm converged.	0,000	0,082	1,17		Algorithm converged.	1,00	1,36	0,0498		0,86		Algorithm converged.	0,73	1,00
	>= 4 positive nodes	582	32,6	166	28,5	604	33,2	155	25,7	1,16		Algorithm converged.	0,89	1,49	0,029		Algorithm converged.	-0,022	0,079	1,11		Algorithm converged.	0,92	1,34	0,2680		0,90		Algorithm converged.	0,75	1,08
Geographical region II	USA/Canada	262	14,7	65	24,8	252	13,8	71	28,2	0,84		Algorithm converged.	0,57	1,25	-0,034		Algorithm converged.	-0,110	0,043	0,88		Algorithm converged.	0,66	1,18	0,3877	0,1092	1,14		Algorithm converged.	0,85	1,52
	Western Europe	814	45,7	261	32,1	824	45,2	226	27,4	1,25		Algorithm converged.	1,01	1,54	0,046		Algorithm converged.	0,002	0,091	1,17		Algorithm converged.	1,01	1,36	0,0405		0,86		Algorithm converged.	0,74	0,99
	Asia Pacific	482	27,0	134	27,8	517	28,4	115	22,2	1,35		Algorithm converged.	1,01	1,79	0,056		Algorithm converged.	0,002	0,109	1,25		Algorithm converged.	1,01	1,55	0,0431		0,80		Algorithm converged.	0,64	0,99
	Latin America	42	2,4	14	33,3	45	2,5	6	13,3	3,25		Algorithm converged.	1,11	9,50	0,200		Algorithm converged.	0,026	0,374	2,50		Algorithm converged.	1,06	5,90	0,0365		0,40		Algorithm converged.	0,17	0,94
	Other	183	10,3	35	19,1	184	10,1	28	15,2	1,32		Algorithm converged.	0,76	2,27	0,039		Algorithm converged.	-0,038	0,116	1,26		Algorithm converged.	0,80	1,98	0,3225		0,80		Algorithm converged.	0,51	1,25
Age II	< 65	1564	87,7	411	26,3	1601	87,9	366	22,9	1,20		Algorithm converged.	1,02	1,41	0,034		Algorithm converged.	0,004	0,064	1,15		Algorithm converged.	1,02	1,30	0,0257	0,5822	0,87		Algorithm converged.	0,77	0,98
	>= 65	219	12,3	98	44,7	221	12,1	80	36,2	1,43		Algorithm converged.	0,97	2,09	0,085		Algorithm converged.	-0,006	0,177	1,24		Algorithm converged.	0,98	1,55	0,0692		0,81		Algorithm converged.	0,64	1,02

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AESAE_S1.xls
10JUN2020 11:45

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	219	12,3	1822	100,0	219	12,0	1,02		Algorithm converged.	0,84	1,25	0,003		Algorithm converged.	-0,019	0,024	1,02		Algorithm converged.	0,86	1,22	0,8091		0,98		Algorithm converged.	0,82	1,17
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,2445	0,81		Algorithm converged.	0,24	2,68
	0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	42	15,5	0,66		Algorithm converged.	0,40	1,10	-0,047		Algorithm converged.	-0,104	0,010	0,70		Algorithm converged.	0,45	1,09	0,1141		1,43		Algorithm converged.	0,92	2,24
	1-3 positive nodes	891	50,0	110	12,3	905	49,7	109	12,0	1,03		Algorithm converged.	0,78	1,36	0,003		Algorithm converged.	-0,027	0,033	1,03		Algorithm converged.	0,80	1,31	0,8452		0,98		Algorithm converged.	0,76	1,25
	>= 4 positive nodes	582	32,6	75	12,9	604	33,2	64	10,6	1,25		Algorithm converged.	0,88	1,78	0,023		Algorithm converged.	-0,014	0,060	1,22		Algorithm converged.	0,89	1,66	0,2211		0,82		Algorithm converged.	0,60	1,13
Geographical region II	USA/Canada	262	14,7	41	15,6	252	13,8	30	11,9	1,37		Algorithm converged.	0,83	2,28	0,037		Algorithm converged.	-0,022	0,097	1,31		Algorithm converged.	0,85	2,04	0,2211	-	0,76		Algorithm converged.	0,49	1,18
	Western Europe	814	45,7	118	14,5	824	45,2	125	15,2	0,95		Algorithm converged.	0,72	1,25	-0,007		Algorithm converged.	-0,041	0,028	0,96		Algorithm converged.	0,76	1,21	0,7014		1,05		Algorithm converged.	0,83	1,32
	Asia Pacific	482	27,0	36	7,5	517	28,4	41	7,9	0,94		Algorithm converged.	0,59	1,49	-0,005		Algorithm converged.	-0,038	0,028	0,94		Algorithm converged.	0,61	1,45	0,7847		1,06		Algorithm converged.	0,69	1,63
	Latin America	42	2,4	5	11,9	45	2,5	4	8,9	1,39		Algorithm converged.	0,35	5,55	0,030		Algorithm converged.	-0,098	0,159	1,34		Algorithm converged.	0,39	4,65	0,6458		0,75		Algorithm converged.	0,21	2,60
	Other	183	10,3	19	10,4	184	10,1	19	10,3	1,01		Algorithm converged.	0,51	1,97	0,001		Algorithm converged.	-0,062	0,063	1,01		Algorithm converged.	0,55	1,84	0,9858		0,99		Algorithm converged.	0,54	1,82
Age II	< 65	1564	87,7	161	10,3	1601	87,9	163	10,2	1,01		Algorithm converged.	0,80	1,27	0,001		Algorithm converged.	-0,020	0,022	1,01		Algorithm converged.	0,82	1,24	0,9165	0,8633	0,99		Algorithm converged.	0,80	1,22

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	58	26,5	221	12,1	56	25,3	1,06		Algorithm converged.	0,69	1,63	0,011		Algorithm converged.	-0,070	0,093	1,05		Algorithm converged.	0,76	1,43	0,7841		0,96		Algorithm converged.	0,70	1,31

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/saf_raw_26c_19JUN2019_CHNS_AEDISC_S1.xls
10JUN2020 11:49

Verträglichkeit (Datenschnitt: 10.01.2022)

Responder Analysen

Generelle Verträglichkeit

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO											PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	1782	>99.9	1822	100,0	1813	99,5	8,85		Algorithm converged.	1,12	69,90	0,004		Algorithm converged.	0,001	0,008	1,00	*	WARNING: The relative Hessian convergence criterion of 0.0001383416 is greater than the limit of 0.0001. The convergence is questionable.	1,00	1,01	0,0101		1,00	*	WARNING: The relative Hessian convergence criterion of 0.0001383416 is greater than the limit of 0.0001. The convergence is questionable.	0,99	1,00
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	51	100,0	42	2,3	42	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE	NE			NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	259	100,0	271	14,9	269	99,3	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	1-3 positive nodes	891	50,0	891	100,0	905	49,7	900	99,4	>999		Algorithm converged.	0,00	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 22.4188861 is greater than the limit of 0.0001. The convergence is questionable.	-0,042	0,097	1,03	*	WARNING: The relative Hessian convergence criterion of 177964749392 is greater than the limit of 0.0001. The convergence is questionable.	0,00	NE	1,0000		0,97	*	WARNING: The relative Hessian convergence criterion of 177964749392 is greater than the limit of 0.0001. The convergence is questionable.	0,00	NE
	>= 4 positive nodes	582	32,6	581	99,8	604	33,2	602	99,7	1,93		Algorithm converged.	0,17	21,34	0,002		Algorithm converged.	-0,004	0,007	1,00		Algorithm converged.	1,00	1,01	0,5829		1,00		Algorithm converged.	0,99	1,00
Geographical region II	USA/Canada	262	14,7	262	100,0	252	13,8	252	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE	NE			NE	NE
	Western Europe	814	45,7	814	100,0	824	45,2	819	99,4	>999		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Asia Pacific	482	27,0	481	99,8	517	28,4	516	99,8	0,93		Algorithm converged.	0,06	14,94	0,000		Algorithm converged.	-0,006	0,005	1,00		Algorithm converged.	0,99	1,01	0,9602		1,00		Algorithm converged.	0,99	1,01
	Latin America	42	2,4	42	100,0	45	2,5	42	93,3	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE
	Other	183	10,3	183	100,0	184	10,1	184	100,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
Age II	< 65	1564	87,7	1563	>99.9	1601	87,9	1593	99,5	7,85		Algorithm converged.	0,98	62,83	0,004		Algorithm converged.	0,001	0,008	1,00		Algorithm converged.	1,00	1,01	0,0203	1,0000	1,00		Algorithm converged.	0,99	1,00

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk		Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	>= 65	219	12,3	219	100,0	221	12,1	220	99,5	>999		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_ANYAE_S1.xls
04MAY2022 9:31

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	1142	64,0	1822	100,0	1056	58,0	1,29		Algorithm converged.	1,13	1,48	0,061		Algorithm converged.	0,029	0,093	1,11		Algorithm converged.	1,05	1,16	0,0002		0,90		Algorithm converged.	0,86	0,95
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	32	62,7	42	2,3	22	52,4	1,53		Algorithm converged.	0,67	3,51	0,104		Algorithm converged.	-0,097	0,305	1,20		Algorithm converged.	0,84	1,71	0,3224	0,0589	0,83		Algorithm converged.	0,58	1,19
	0 positive nodes, tumor > 1 cm	259	14,5	177	68,3	271	14,9	143	52,8	1,93		Algorithm converged.	1,36	2,75	0,156		Algorithm converged.	0,074	0,238	1,30		Algorithm converged.	1,13	1,49	0,0003		0,77		Algorithm converged.	0,67	0,89
	1-3 positive nodes	891	50,0	568	63,7	905	49,7	551	60,9	1,13		Algorithm converged.	0,93	1,37	0,029		Algorithm converged.	-0,016	0,073	1,05		Algorithm converged.	0,97	1,13	0,2105		0,96		Algorithm converged.	0,89	1,03
	>= 4 positive nodes	582	32,6	365	62,7	604	33,2	340	56,3	1,31		Algorithm converged.	1,04	1,65	0,064		Algorithm converged.	0,008	0,120	1,11		Algorithm converged.	1,01	1,22	0,0245		0,90		Algorithm converged.	0,82	0,99
Geographical region II	USA/Canada	262	14,7	182	69,5	252	13,8	141	56,0	1,79		Algorithm converged.	1,25	2,57	0,135		Algorithm converged.	0,052	0,218	1,24		Algorithm converged.	1,08	1,42	0,0018	0,0088	0,81		Algorithm converged.	0,70	0,92
	Western Europe	814	45,7	518	63,6	824	45,2	520	63,1	1,02		Algorithm converged.	0,84	1,25	0,005		Algorithm converged.	-0,041	0,052	1,01		Algorithm converged.	0,94	1,09	0,8240		0,99		Algorithm converged.	0,92	1,07
	Asia Pacific	482	27,0	340	70,5	517	28,4	305	59,0	1,66		Algorithm converged.	1,28	2,16	0,115		Algorithm converged.	0,057	0,174	1,20		Algorithm converged.	1,09	1,31	0,0001		0,84		Algorithm converged.	0,76	0,92
	Latin America	42	2,4	20	47,6	45	2,5	24	53,3	0,80		Algorithm converged.	0,34	1,85	-0,057		Algorithm converged.	-0,267	0,153	0,89		Algorithm converged.	0,59	1,36	0,5958		1,12		Algorithm converged.	0,74	1,70
	Other	183	10,3	82	44,8	184	10,1	66	35,9	1,45		Algorithm converged.	0,95	2,21	0,089		Algorithm converged.	-0,011	0,189	1,25		Algorithm converged.	0,97	1,61	0,0827		0,80		Algorithm converged.	0,62	1,03
Age II	< 65	1564	87,7	979	62,6	1601	87,9	915	57,2	1,25		Algorithm converged.	1,09	1,45	0,054		Algorithm converged.	0,020	0,089	1,10		Algorithm converged.	1,03	1,16	0,0018	0,3695	0,91		Algorithm converged.	0,86	0,97
	>= 65	219	12,3	163	74,4	221	12,1	141	63,8	1,65		Algorithm converged.	1,10	2,49	0,106		Algorithm converged.	0,021	0,192	1,17		Algorithm converged.	1,03	1,32	0,0166		0,86		Algorithm converged.	0,76	0,97

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AEGR345_S1.xls
04MAY2022 9:33

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	751	42,1	1822	100,0	683	37,5	1,21		Algorithm converged.	1,06	1,39	0,046		Algorithm converged.	0,014	0,078	1,12		Algorithm converged.	1,04	1,22	0,0045		0,89		Algorithm converged.	0,82	0,96
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	18	35,3	42	2,3	14	33,3	1,09		Algorithm converged.	0,46	2,58	0,020		Algorithm converged.	-0,174	0,213	1,06		Algorithm converged.	0,60	1,87	0,8433	0,2110	0,94		Algorithm converged.	0,54	1,66
	0 positive nodes, tumor > 1 cm	259	14,5	113	43,6	271	14,9	89	32,8	1,58		Algorithm converged.	1,11	2,25	0,108		Algorithm converged.	0,026	0,190	1,33		Algorithm converged.	1,07	1,65	0,0112		0,75		Algorithm converged.	0,60	0,94
	1-3 positive nodes	891	50,0	375	42,1	905	49,7	365	40,3	1,08		Algorithm converged.	0,89	1,30	0,018		Algorithm converged.	-0,028	0,063	1,04		Algorithm converged.	0,93	1,17	0,4497		0,96		Algorithm converged.	0,86	1,07
	>= 4 positive nodes	582	32,6	245	42,1	604	33,2	215	35,6	1,32		Algorithm converged.	1,04	1,66	0,065		Algorithm converged.	0,010	0,120	1,18		Algorithm converged.	1,02	1,37	0,0220		0,85		Algorithm converged.	0,73	0,98
Geographical region II	USA/Canada	262	14,7	128	48,9	252	13,8	99	39,3	1,48		Algorithm converged.	1,04	2,10	0,096		Algorithm converged.	0,010	0,181	1,24		Algorithm converged.	1,02	1,51	0,0303	0,0179	0,80		Algorithm converged.	0,66	0,98
	Western Europe	814	45,7	369	45,3	824	45,2	378	45,9	0,98		Algorithm converged.	0,81	1,19	-0,005		Algorithm converged.	-0,054	0,043	0,99		Algorithm converged.	0,89	1,10	0,8257		1,01		Algorithm converged.	0,91	1,12
	Asia Pacific	482	27,0	183	38,0	517	28,4	151	29,2	1,48		Algorithm converged.	1,14	1,93	0,088		Algorithm converged.	0,029	0,146	1,30		Algorithm converged.	1,09	1,55	0,0035		0,77		Algorithm converged.	0,65	0,92
	Latin America	42	2,4	15	35,7	45	2,5	17	37,8	0,92		Algorithm converged.	0,38	2,19	-0,021		Algorithm converged.	-0,223	0,182	0,95		Algorithm converged.	0,54	1,64	0,8421		1,06		Algorithm converged.	0,61	1,84
	Other	183	10,3	56	30,6	184	10,1	38	20,7	1,69		Algorithm converged.	1,05	2,73	0,099		Algorithm converged.	0,011	0,188	1,48		Algorithm converged.	1,04	2,12	0,0311		0,67		Algorithm converged.	0,47	0,96
Age II	< 65	1564	87,7	647	41,4	1601	87,9	598	37,4	1,18		Algorithm converged.	1,03	1,37	0,040		Algorithm converged.	0,006	0,074	1,11		Algorithm converged.	1,02	1,21	0,0209	0,3608	0,90		Algorithm converged.	0,83	0,98
	>= 65	219	12,3	104	47,5	221	12,1	85	38,5	1,45		Algorithm converged.	0,99	2,11	0,090		Algorithm converged.	-0,002	0,182	1,23		Algorithm converged.	0,99	1,53	0,0572		0,81		Algorithm converged.	0,65	1,01

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AEGR3_S1.xls
04MAY2022 9:37

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	382	21,4	1822	100,0	362	19,9	1,10		Algorithm converged.	0,94	1,29	0,016		Algorithm converged.	-0,011	0,042	1,08		Algorithm converged.	0,95	1,23	0,2485		0,93		Algorithm converged.	0,82	1,05
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	12	23,5	42	2,3	8	19,0	1,31		Algorithm converged.	0,48	3,58	0,045		Algorithm converged.	-0,121	0,211	1,24		Algorithm converged.	0,56	2,74	0,6028	0,8296	0,81		Algorithm converged.	0,37	1,79
	0 positive nodes, tumor > 1 cm	259	14,5	63	24,3	271	14,9	54	19,9	1,29		Algorithm converged.	0,86	1,95	0,044		Algorithm converged.	-0,027	0,115	1,22		Algorithm converged.	0,89	1,68	0,2235		0,82		Algorithm converged.	0,59	1,13
	1-3 positive nodes	891	50,0	188	21,1	905	49,7	180	19,9	1,08		Algorithm converged.	0,86	1,35	0,012		Algorithm converged.	-0,025	0,049	1,06		Algorithm converged.	0,88	1,27	0,5252		0,94		Algorithm converged.	0,79	1,13
	>= 4 positive nodes	582	32,6	119	20,4	604	33,2	120	19,9	1,04		Algorithm converged.	0,78	1,38	0,006		Algorithm converged.	-0,040	0,051	1,03		Algorithm converged.	0,82	1,29	0,8037		0,97		Algorithm converged.	0,77	1,22
Geographical region II	USA/Canada	262	14,7	54	20,6	252	13,8	41	16,3	1,34		Algorithm converged.	0,85	2,09	0,043		Algorithm converged.	-0,023	0,110	1,27		Algorithm converged.	0,88	1,83	0,2070	0,7574	0,79		Algorithm converged.	0,55	1,14
	Western Europe	814	45,7	146	17,9	824	45,2	136	16,5	1,11		Algorithm converged.	0,86	1,43	0,014		Algorithm converged.	-0,022	0,051	1,09		Algorithm converged.	0,88	1,34	0,4432		0,92		Algorithm converged.	0,74	1,14
	Asia Pacific	482	27,0	152	31,5	517	28,4	151	29,2	1,12		Algorithm converged.	0,85	1,46	0,023		Algorithm converged.	-0,034	0,080	1,08		Algorithm converged.	0,89	1,30	0,4237		0,93		Algorithm converged.	0,77	1,12
	Latin America	42	2,4	4	9,5	45	2,5	7	15,6	0,57		Algorithm converged.	0,15	2,11	-0,060		Algorithm converged.	-0,199	0,078	0,61		Algorithm converged.	0,19	1,94	0,4048		1,63		Algorithm converged.	0,51	5,18
	Other	183	10,3	26	14,2	184	10,1	27	14,7	0,96		Algorithm converged.	0,54	1,72	-0,005		Algorithm converged.	-0,077	0,067	0,97		Algorithm converged.	0,59	1,59	0,8989		1,03		Algorithm converged.	0,63	1,70
Age II	< 65	1564	87,7	326	20,8	1601	87,9	311	19,4	1,09		Algorithm converged.	0,92	1,30	0,014		Algorithm converged.	-0,014	0,042	1,07		Algorithm converged.	0,93	1,23	0,3198	0,8604	0,93		Algorithm converged.	0,81	1,07
	>= 65	219	12,3	56	25,6	221	12,1	51	23,1	1,15		Algorithm converged.	0,74	1,77	0,025		Algorithm converged.	-0,055	0,105	1,11		Algorithm converged.	0,80	1,54	0,5424		0,90		Algorithm converged.	0,65	1,26

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AEGR4_S1.xls
04MAY2022 9:39

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk	Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	9	0,5	1822	100,0	11	0,6	0,84		Algorithm converged.	0,35	2,02	-0,001		Algorithm converged.	-0,006	0,004	0,84		Algorithm converged.	0,35	2,01	0,6896		1,20		Algorithm converged.	0,50	2,88
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.911413 3947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	1-3 positive nodes	891	50,0	5	0,6	905	49,7	6	0,7	0,85		Algorithm converged.	0,26	2,78	-0,001		Algorithm converged.	-0,008	0,006	0,85		Algorithm converged.	0,26	2,76	0,7824		1,18		Algorithm converged.	0,36	3,86
	>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001	0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference					Relative Risk						Relative Risk				Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
	Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
	Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
	Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
Age II	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
	>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AEGR5_S1.xls
04MAY2022 9:40

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	509	28,5	1822	100,0	446	24,5	1,23		Algorithm converged.	1,06	1,43	0,041		Algorithm converged.	0,012	0,069	1,17		Algorithm converged.	1,05	1,30	0,0057		0,86		Algorithm converged.	0,77	0,96
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	17	33,3	42	2,3	11	26,2	1,41		Algorithm converged.	0,57	3,47	0,071		Algorithm converged.	-0,114	0,257	1,27		Algorithm converged.	0,67	2,41	0,4595	0,8815	0,79		Algorithm converged.	0,41	1,49
	0 positive nodes, tumor > 1 cm	259	14,5	73	28,2	271	14,9	60	22,1	1,38		Algorithm converged.	0,93	2,05	0,060		Algorithm converged.	-0,013	0,134	1,27		Algorithm converged.	0,95	1,71	0,1100		0,79		Algorithm converged.	0,58	1,06
	1-3 positive nodes	891	50,0	253	28,4	905	49,7	220	24,3	1,23		Algorithm converged.	1,00	1,52	0,041		Algorithm converged.	0,000	0,082	1,17		Algorithm converged.	1,00	1,36	0,0498		0,86		Algorithm converged.	0,73	1,00
	>= 4 positive nodes	582	32,6	166	28,5	604	33,2	155	25,7	1,16		Algorithm converged.	0,89	1,49	0,029		Algorithm converged.	-0,022	0,079	1,11		Algorithm converged.	0,92	1,34	0,2680		0,90		Algorithm converged.	0,75	1,08
Geographical region II	USA/Canada	262	14,7	65	24,8	252	13,8	71	28,2	0,84		Algorithm converged.	0,57	1,25	-0,034		Algorithm converged.	-0,110	0,043	0,88		Algorithm converged.	0,66	1,18	0,3877	0,1092	1,14		Algorithm converged.	0,85	1,52
	Western Europe	814	45,7	261	32,1	824	45,2	226	27,4	1,25		Algorithm converged.	1,01	1,54	0,046		Algorithm converged.	0,002	0,091	1,17		Algorithm converged.	1,01	1,36	0,0405		0,86		Algorithm converged.	0,74	0,99
	Asia Pacific	482	27,0	134	27,8	517	28,4	115	22,2	1,35		Algorithm converged.	1,01	1,79	0,056		Algorithm converged.	0,002	0,109	1,25		Algorithm converged.	1,01	1,55	0,0431		0,80		Algorithm converged.	0,64	0,99
	Latin America	42	2,4	14	33,3	45	2,5	6	13,3	3,25		Algorithm converged.	1,11	9,50	0,200		Algorithm converged.	0,026	0,374	2,50		Algorithm converged.	1,06	5,90	0,0365		0,40		Algorithm converged.	0,17	0,94
	Other	183	10,3	35	19,1	184	10,1	28	15,2	1,32		Algorithm converged.	0,76	2,27	0,039		Algorithm converged.	-0,038	0,116	1,26		Algorithm converged.	0,80	1,98	0,3225		0,80		Algorithm converged.	0,51	1,25
Age II	< 65	1564	87,7	411	26,3	1601	87,9	366	22,9	1,20		Algorithm converged.	1,02	1,41	0,034		Algorithm converged.	0,004	0,064	1,15		Algorithm converged.	1,02	1,30	0,0257	0,5822	0,87		Algorithm converged.	0,77	0,98
	>= 65	219	12,3	98	44,7	221	12,1	80	36,2	1,43		Algorithm converged.	0,97	2,09	0,085		Algorithm converged.	-0,006	0,177	1,24		Algorithm converged.	0,98	1,55	0,0692		0,81		Algorithm converged.	0,64	1,02

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESAE_S1.xls
04MAY2022 9:42

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference				Relative Risk							Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	220	12,3	1822	100,0	219	12,0	1,03		Algorithm converged.	0,84	1,26	0,003		Algorithm converged.	-0,018	0,025	1,03		Algorithm converged.	0,86	1,22	0,7697		0,97		Algorithm converged.	0,82	1,16
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,2438	0,81		Algorithm converged.	0,24	2,68
	0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	42	15,5	0,66		Algorithm converged.	0,40	1,10	-0,047		Algorithm converged.	-0,104	0,010	0,70		Algorithm converged.	0,45	1,09	0,1141		1,43		Algorithm converged.	0,92	2,24
	1-3 positive nodes	891	50,0	111	12,5	905	49,7	109	12,0	1,04		Algorithm converged.	0,78	1,38	0,004		Algorithm converged.	-0,026	0,034	1,03		Algorithm converged.	0,81	1,32	0,7892		0,97		Algorithm converged.	0,75	1,24
	>= 4 positive nodes	582	32,6	75	12,9	604	33,2	64	10,6	1,25		Algorithm converged.	0,88	1,78	0,023		Algorithm converged.	-0,014	0,060	1,22		Algorithm converged.	0,89	1,66	0,2211		0,82		Algorithm converged.	0,60	1,13
Geographical region II	USA/Canada	262	14,7	42	16,0	252	13,8	30	11,9	1,41		Algorithm converged.	0,85	2,34	0,041		Algorithm converged.	-0,019	0,101	1,35		Algorithm converged.	0,87	2,08	0,1805	-	0,74		Algorithm converged.	0,48	1,15
	Western Europe	814	45,7	118	14,5	824	45,2	125	15,2	0,95		Algorithm converged.	0,72	1,25	-0,007		Algorithm converged.	-0,041	0,028	0,96		Algorithm converged.	0,76	1,21	0,7014		1,05		Algorithm converged.	0,83	1,32
	Asia Pacific	482	27,0	36	7,5	517	28,4	41	7,9	0,94		Algorithm converged.	0,59	1,49	-0,005		Algorithm converged.	-0,038	0,028	0,94		Algorithm converged.	0,61	1,45	0,7847		1,06		Algorithm converged.	0,69	1,63
	Latin America	42	2,4	5	11,9	45	2,5	4	8,9	1,39		Algorithm converged.	0,35	5,55	0,030		Algorithm converged.	-0,098	0,159	1,34		Algorithm converged.	0,39	4,65	0,6458		0,75		Algorithm converged.	0,21	2,60
	Other	183	10,3	19	10,4	184	10,1	19	10,3	1,01		Algorithm converged.	0,51	1,97	0,001		Algorithm converged.	-0,062	0,063	1,01		Algorithm converged.	0,55	1,84	0,9858		0,99		Algorithm converged.	0,54	1,82
Age II	< 65	1564	87,7	162	10,4	1601	87,9	163	10,2	1,02		Algorithm converged.	0,81	1,28	0,002		Algorithm converged.	-0,019	0,023	1,02		Algorithm converged.	0,83	1,25	0,8698	0,8886	0,98		Algorithm converged.	0,80	1,21
	>= 65	219	12,3	58	26,5	221	12,1	56	25,3	1,06		Algorithm converged.	0,69	1,63	0,011		Algorithm converged.	-0,070	0,093	1,05		Algorithm converged.	0,76	1,43	0,7841		0,96		Algorithm converged.	0,70	1,31

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AEDISC_S1.xls
04MAY2022 9:43

Verträglichkeit (Datenschnitt: 10.01.2022)

Responder Analysen

Generelle Verträglichkeit nach SOC/PT

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	942	52,8	1822	100,0	885	48,6	1,19		Algorithm converged.	1,04	1,35	0,043		Algorithm converged.	0,010	0,075	1,09		Algorithm converged.	1,02	1,16	0,0106		0,92		Algorithm converged.	0,86	0,98
	AGRANULOCYTOSIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	ANAEMIA	n/a	1783	100,0	504	28,3	1822	100,0	433	23,8	1,26		Algorithm converged.	1,09	1,47	0,045		Algorithm converged.	0,016	0,074	1,19		Algorithm converged.	1,06	1,33	0,0021		0,84		Algorithm converged.	0,75	0,94
	ANAEMIA MACROCYTIC	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	BLOOD DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BONE MARROW FAILURE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED INTRAVASCULAR COAGULATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EOSINOPHILIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ERYTHROPENIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE NEUTROPENIA	n/a	1783	100,0	212	11,9	1822	100,0	190	10,4	1,16		Algorithm converged.	0,94	1,43	0,015		Algorithm converged.	-0,006	0,035	1,14		Algorithm converged.	0,95	1,37	0,1636		0,88		Algorithm converged.	0,73	1,05
	GRANULOCYTOPENIA	n/a	1783	100,0	15	0,8	1822	100,0	19	1,0	0,81		Algorithm converged.	0,41	1,59	-0,002		Algorithm converged.	-0,008	0,004	0,81		Algorithm converged.	0,41	1,58	0,5322		1,24		Algorithm converged.	0,63	2,43
	HAEMATOTOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	HAEMOGLOBINAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOLYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERLEUKOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	INCREASED TENDENCY TO BRUISE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IRON DEFICIENCY ANAEMIA	n/a	1783	100,0	10	0,6	1822	100,0	2	0,1	5,13		Algorithm converged.	1,12	23,46	0,005		Algorithm converged.	0,001	0,008	5,11		Algorithm converged.	1,12	23,29	0,0351		0,20		Algorithm converged.	0,04	0,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	LEUKOCYTOSIS	n/a	1783	100,0	10	0,6	1822	100,0	6	0,3	1,71		Algorithm converged.	0,62	4,71	0,002		Algorithm converged.	-0,002	0,007		1,70		Algorithm converged.	0,62	4,68	0,3015			0,59		Algorithm converged.	0,21	1,61						
	LEUKOPENIA	n/a	1783	100,0	167	9,4	1822	100,0	189	10,4	0,89		Algorithm converged.	0,72	1,11	-0,010		Algorithm converged.	-0,030	0,009		0,90		Algorithm converged.	0,74	1,10	0,3112			1,11		Algorithm converged.	0,91	1,35						
	LYMPH NODE PAIN	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHADENITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHADENOPATHY	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005		1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	LYMPHOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOID TISSUE HYPERPLASIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOPENIA	n/a	1783	100,0	11	0,6	1822	100,0	10	0,5	1,12		Algorithm converged.	0,48	2,66	0,001		Algorithm converged.	-0,004	0,006	1,12		Algorithm converged.	0,48	2,64	0,7884		0,89		Algorithm converged.	0,38	2,09
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROCYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MICROCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELOSUPPRESSION	n/a	1783	100,0	8	0,4	1822	100,0	13	0,7	0,63		Algorithm converged.	0,26	1,52	-0,003		Algorithm converged.	-0,008	0,002	0,63		Algorithm converged.	0,26	1,51	0,3006		1,59		Algorithm converged.	0,66	3,83
	NEUTROPENIA	n/a	1783	100,0	468	26,2	1822	100,0	431	23,7	1,15		Algorithm converged.	0,99	1,34	0,026		Algorithm converged.	-0,002	0,054	1,11		Algorithm converged.	0,99	1,24	0,0722		0,90		Algorithm converged.	0,80	1,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	NEUTROPHILIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593			0,49		Algorithm converged.	0,04	5,39	
	NORMOCHROMIC NORMOCYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	PANCYTOPENIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834			1,96		Algorithm converged.	0,18	21,57	
	THROMBOCYTOPENIA	n/a	1783	100,0	75	4,2	1822	100,0	67	3,7	1,15		Algorithm converged.	0,82	1,61	0,005		Algorithm converged.	-0,007	0,018		1,14		Algorithm converged.	0,83	1,58	0,4146			0,87		Algorithm converged.	0,63	1,21	
	THROMBOCYTOSIS	n/a	1783	100,0	8	0,4	1822	100,0	1	<0.1	8,21		Algorithm converged.	1,03	65,69	0,004		Algorithm converged.	0,001	0,007		8,17		Algorithm converged.	1,02	65,29	0,0475			0,12		Algorithm converged.	0,02	0,98	
CARDIAC DISORDER	-Total	n/a	1783	100,0	208	11,7	1822	100,0	198	10,9	1,08		Algorithm converged.	0,88	1,33	0,008		Algorithm converged.	-0,013	0,029		1,07		Algorithm converged.	0,89	1,29	0,4484			0,93		Algorithm converged.	0,78	1,12	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANGINA PECTORIS	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	AORTIC VALVE INCOMPETENCE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	AORTIC VALVE SCLEROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ARRHYTHMIA	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003		0,88		Algorithm converged.	0,29	2,60	0,8114			1,14		Algorithm converged.	0,38	3,39	
	ARTERIOSCLEROSIS CORONARY ARTERY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL FIBRILLATION	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	ATRIAL TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ATRIAL THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BIFASCICULAR BLOCK	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRADYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BUNDLE BRANCH BLOCK	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BUNDLE BRANCH BLOCK LEFT	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BUNDLE BRANCH BLOCK RIGHT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC ANEURYSM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIAC DISORDER	n/a	1783	100,0	7	0,4	1822	100,0	1	<0.1	7,18		Algorithm converged.	0,88	58,40	0,003		Algorithm converged.	0,000	0,006	7,15		Algorithm converged.	0,88	58,08	0,0656		0,14		Algorithm converged.	0,02	1,14
	CARDIAC FAILURE	n/a	1783	100,0	25	1,4	1822	100,0	13	0,7	1,98		Algorithm converged.	1,01	3,88	0,007		Algorithm converged.	0,000	0,014	1,97		Algorithm converged.	1,01	3,83	0,0471		0,51		Algorithm converged.	0,26	0,99
	CARDIAC FAILURE CONGESTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIOMYOPATHY	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	CARDIOVASCULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	CARDIOVASCULAR INSUFFICIENCY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	CONDUCTION DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	CORONARY ARTERY STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	DIASTOLIC DYSFUNCTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	EXTRASYSTOLES	n/a	1783	100,0	6	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	HEART VALVE INCOMPETENCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSIVE CARDIOMYOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE HEART DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEFT VENTRICULAR DILATATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LEFT VENTRICULAR DYSFUNCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LEFT VENTRICULAR HYPERTROPHY	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	METABOLIC CARDIOMYOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MITRAL VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MITRAL VALVE INCOMPETENCE	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84
	MITRAL VALVE PROLAPSE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	MYOCARDIAL ISCHAEMIA	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NODAL RHYTHM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALPITATIONS	n/a	1783	100,0	77	4,3	1822	100,0	79	4,3	1,00		Algorithm converged.	0,72	1,37	0,000		Algorithm converged.	-0,013	0,013	1,00		Algorithm converged.	0,73	1,35	0,9796		1,00		Algorithm converged.	0,74	1,36
	PERICARDIAL EFFUSION	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3	1,36		Algorithm converged.	0,47	3,94	0,001		Algorithm converged.	-0,003	0,005	1,36		Algorithm converged.	0,47	3,92	0,5661		0,73		Algorithm converged.	0,26	2,11
	PRINZMETAL ANGINA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS ARRHYTHMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	SINUS BRADYCARDIA	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004		1,70		Algorithm converged.	0,41	7,12	0,4655			0,59		Algorithm converged.	0,14	2,45
	SINUS NODE DYSFUNCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS TACHYCARDIA	n/a	1783	100,0	12	0,7	1822	100,0	12	0,7	1,02		Algorithm converged.	0,46	2,28	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,46	2,27	0,9576		0,98		Algorithm converged.	0,44	2,17
	STRESS CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUPRAVENTRICULAR EXTRASYSTOLES	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	SUPRAVENTRICULAR TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYARRHYTHMIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYCARDIA	n/a	1783	100,0	44	2,5	1822	100,0	32	1,8	1,42		Algorithm converged.	0,89	2,24	0,007		Algorithm converged.	-0,002	0,017	1,41		Algorithm converged.	0,90	2,21	0,1391		0,71		Algorithm converged.	0,45	1,12
	TACHYCARDIA PAROXYSMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRICUSPID VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TRICUSPID VALVE INCOMPETENCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	VENTRICULAR EXTRASYSTOLES	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000		0,20		Algorithm converged.	0,02	1,75	0,1470			4,89		Algorithm converged.	0,57	41,84	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000		0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CYSTIC FIBROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHALANGEAL HYPOPLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYLORIC STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TYPE V HYPERLIPIDAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
EAR AND LABYRINTH DISORDER	-Total	n/a	1783	100,0	122	6,8	1822	100,0	131	7,2	0,95		Algorithm converged.	0,73	1,22	-0,003		Algorithm converged.	-0,020	0,013	0,95		Algorithm converged.	0,75	1,21	0,6831		1,05		Algorithm converged.	0,83	1,33
	CERUMEN IMPACTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONDUCTIVE DEAFNESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEAFNESS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	DEAFNESS BILATERAL	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEAFNESS UNILATERAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EAR CONGESTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	EAR DISCOMFORT	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	EAR DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	EAR PAIN	n/a	1783	100,0	14	0,8	1822	100,0	14	0,8	1,02		Algorithm converged.	0,49	2,15	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,49	2,14	0,9542		0,98		Algorithm converged.	0,47	2,05
	EXTERNAL EAR INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOACUSIS	n/a	1783	100,0	3	0,2	1822	100,0	9	0,5	0,34		Algorithm converged.	0,09	1,26	-0,003		Algorithm converged.	-0,007	0,000	0,34		Algorithm converged.	0,09	1,26	0,1058		2,94		Algorithm converged.	0,80	10,83
	MENIERE'S DISEASE	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	MIDDLE EAR INFLAMMATION	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTOLITHIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTOTOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PRESBYACUSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TINNITUS	n/a	1783	100,0	29	1,6	1822	100,0	30	1,6	0,99		Algorithm converged.	0,59	1,65	0,000		Algorithm converged.	-0,008	0,008	0,99		Algorithm converged.	0,60	1,64	0,9621		1,01		Algorithm converged.	0,61	1,68
	TYMPANIC MEMBRANE PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERTIGO	n/a	1783	100,0	57	3,2	1822	100,0	64	3,5	0,91		Algorithm converged.	0,63	1,30	-0,003		Algorithm converged.	-0,015	0,009	0,91		Algorithm converged.	0,64	1,29	0,5988		1,10		Algorithm converged.	0,77	1,56
	VERTIGO POSITIONAL	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
ENDOCRINE DISORDER	-Total	n/a	1783	100,0	17	1,0	1822	100,0	24	1,3	0,72		Algorithm converged.	0,39	1,35	-0,004		Algorithm converged.	-0,011	0,003		0,72		Algorithm converged.	0,39	1,34	0,3053		1,38		Algorithm converged.	0,74	2,56
	AUTOIMMUNE THYROIDITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CUSHING'S SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CUSHINGOID	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	GOITRE	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	HYPERPARATHYROIDISM PRIMARY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPROLACTINAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001		0,34		Algorithm converged.	0,04	3,27	0,3508			2,94		Algorithm converged.	0,31	28,20
	HYPOTHYROIDISM	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003		0,73		Algorithm converged.	0,23	2,30	0,5902			1,37		Algorithm converged.	0,44	4,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STEROID WITHDRAWAL SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID CYST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THYROID DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	THYROID MASS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	THYROID PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
EYE DISORDER	-Total	n/a	1783	100,0	455	25,5	1822	100,0	452	24,8	1,04		Algorithm converged.	0,89	1,21	0,007		Algorithm converged.	-0,021	0,035	1,03		Algorithm converged.	0,92	1,15	0,6229		0,97		Algorithm converged.	0,87	1,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk									Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	ABNORMAL SENSATION IN EYE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	AMAUROSIS FUGAX	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMBLYOPIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASTHENOPIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ASTIGMATISM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLEPHARITIS	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLEPHARITIS ALLERGIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLEPHAROSPASM	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003		0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	CATARACT	n/a	1783	100,0	3	0,2	1822	100,0	11	0,6	0,28		Algorithm converged.	0,08	1,00	-0,004		Algorithm converged.	-0,008	0,000		0,28		Algorithm converged.	0,08	1,00	0,0495		3,59		Algorithm converged.	1,00	12,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARACT CORTICAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHALAZION	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	CONJUNCTIVAL DEPOSIT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONJUNCTIVAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	CONJUNCTIVAL HYPERAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63						
	CONJUNCTIVITIS ALLERGIC	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001		0,26		Algorithm converged.	0,03	2,28	0,2220			3,91		Algorithm converged.	0,44	34,99						
	CORNEAL EXFOLIATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DACRYOSTENOSIS ACQUIRED	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIPLOPIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	DRY EYE	n/a	1783	100,0	93	5,2	1822	100,0	80	4,4	1,20		Algorithm converged.	0,88	1,63	0,008		Algorithm converged.	-0,006	0,022	1,19		Algorithm converged.	0,89	1,59	0,2472		0,84		Algorithm converged.	0,63	1,13
	ECTROPION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk								
	ERYTHEMA OF EYELID	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	EYE ALLERGY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	EYE DISCHARGE	n/a	1783	100,0	4	0,2	1822	100,0	8	0,4	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,006	0,002		0,51		Algorithm converged.	0,15	1,69	0,2721			1,96		Algorithm converged.	0,59	6,49	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE DISORDER	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	EYE HAEMORRHAGE	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	EYE INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYE IRRITATION	n/a	1783	100,0	11	0,6	1822	100,0	9	0,5	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,006	1,25		Algorithm converged.	0,52	3,01	0,6199		0,80		Algorithm converged.	0,33	1,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE MOVEMENT DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYE OEDEMA	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.20442909 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE PAIN	n/a	1783	100,0	14	0,8	1822	100,0	13	0,7	1,10		Algorithm converged.	0,52	2,35	0,001		Algorithm converged.	-0,005	0,006	1,10		Algorithm converged.	0,52	2,33	0,8030		0,91		Algorithm converged.	0,43	1,93
	EYE PRURITUS	n/a	1783	100,0	9	0,5	1822	100,0	5	0,3	1,84		Algorithm converged.	0,62	5,51	0,002		Algorithm converged.	-0,002	0,006	1,84		Algorithm converged.	0,62	5,48	0,2737		0,54		Algorithm converged.	0,18	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk									Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL								
	EYE SWELLING	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39								
	EYELID FUNCTION DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63								
	EYELID MARGIN CRUSTING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE								
	EYELID OEDEMA	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49								

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID PTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYELID RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID SKIN DRYNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYELIDS PRURITUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOREIGN BODY SENSATION IN EYES	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	GLAUCOMA	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	KERATITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004		4,09		Algorithm converged.	0,46	36,53	0,2077			0,24		Algorithm converged.	0,03	2,19
	KERATOCONUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
	KERATOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE									
	LACRIMATION DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LACRIMATION DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LACRIMATION INCREASED	n/a	1783	100,0	228	12,8	1822	100,0	247	13,6	0,93		Algorithm converged.	0,77	1,13	-0,008		Algorithm converged.	-0,030	0,014	0,94		Algorithm converged.	0,80	1,12	0,4950		1,06		Algorithm converged.	0,90	1,25
	MACULAR OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MEIBOMIAN GLAND DYSFUNCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	METAMORPHOPSIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOPIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NONINFECTIVE CONJUNCTIVITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OCULAR DISCOMFORT	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81
	OCULAR HYPERAEMIA	n/a	1783	100,0	9	0,5	1822	100,0	4	0,2	2,31		Algorithm converged.	0,71	7,50	0,003		Algorithm converged.	-0,001	0,007	2,30		Algorithm converged.	0,71	7,45	0,1653		0,43		Algorithm converged.	0,13	1,41
	OCULAR HYPERTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OCULAR TOXICITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	OPHTHALMOPLEGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OPTIC NERVE DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORBITAL GRANULOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLOEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERIORBITAL OEDEMA	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	PERIORBITAL SWELLING	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PHOTOPHOBIA	n/a	1783	100,0	6	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHOTOPSIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PTERYGIUM	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	RETINAL DETACHMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	RETINAL VASCULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SCLERAL DISORDER	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	SCLERAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ULCERATIVE KERATITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UVEITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERNAL KERATOCONJUNCTIVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VISION BLURRED	n/a	1783	100,0	40	2,2	1822	100,0	44	2,4	0,93		Algorithm converged.	0,60	1,43	-0,002		Algorithm converged.	-0,012	0,008	0,93		Algorithm converged.	0,61	1,42	0,7329		1,08		Algorithm converged.	0,71	1,64
	VISUAL ACUITY REDUCED	n/a	1783	100,0	10	0,6	1822	100,0	6	0,3	1,71		Algorithm converged.	0,62	4,71	0,002		Algorithm converged.	-0,002	0,007	1,70		Algorithm converged.	0,62	4,68	0,3015		0,59		Algorithm converged.	0,21	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk								
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VISUAL FIELD DEFECT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	VISUAL IMPAIRMENT	n/a	1783	100,0	37	2,1	1822	100,0	21	1,2	1,82		Algorithm converged.	1,06	3,12	0,009		Algorithm converged.	0,001	0,017		1,80		Algorithm converged.	1,06	3,06	0,0301			0,56		Algorithm converged.	0,33	0,95	
	VITREOUS DETACHMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS FLOATERS	n/a	1783	100,0	8	0,4	1822	100,0	4	0,2	2,05		Algorithm converged.	0,62	6,81	0,002		Algorithm converged.	-0,001	0,006	2,04		Algorithm converged.	0,62	6,77	0,2424		0,49		Algorithm converged.	0,15	1,62
	VITREOUS HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VITREOUS OPACITIES	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	XEROPHTHALMIA	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	1687	94,6	1822	100,0	1630	89,5	2,07		Algorithm converged.	1,61	2,67	0,052		Algorithm converged.	0,034	0,069	1,06		Algorithm converged.	1,04	1,08	<.0001		0,95		Algorithm converged.	0,93	0,96
	ABDOMINAL DISCOMFORT	n/a	1783	100,0	18	1,0	1822	100,0	27	1,5	0,68		Algorithm converged.	0,37	1,24	-0,005		Algorithm converged.	-0,012	0,003	0,68		Algorithm converged.	0,38	1,23	0,2044		1,47		Algorithm converged.	0,81	2,66
	ABDOMINAL DISTENSION	n/a	1783	100,0	56	3,1	1822	100,0	41	2,3	1,41		Algorithm converged.	0,94	2,12	0,009		Algorithm converged.	-0,002	0,019	1,40		Algorithm converged.	0,94	2,08	0,1002		0,72		Algorithm converged.	0,48	1,07
	ABDOMINAL HERNIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABDOMINAL PAIN	n/a	1783	100,0	200	11,2	1822	100,0	189	10,4	1,09		Algorithm converged.	0,88	1,35	0,008		Algorithm converged.	-0,012	0,029	1,08		Algorithm converged.	0,90	1,30	0,4144		0,92		Algorithm converged.	0,77	1,12
	ABDOMINAL PAIN LOWER	n/a	1783	100,0	4	0,2	1822	100,0	8	0,4	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,15	1,69	0,2721		1,96		Algorithm converged.	0,59	6,49
	ABDOMINAL PAIN UPPER	n/a	1783	100,0	175	9,8	1822	100,0	156	8,6	1,16		Algorithm converged.	0,93	1,46	0,013		Algorithm converged.	-0,006	0,031	1,15		Algorithm converged.	0,93	1,41	0,1932		0,87		Algorithm converged.	0,71	1,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ABDOMINAL RIGIDITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ABNORMAL FAECES	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	ACID PEPTIC DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	AEROPHAGIA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ANAESTHESIA ORAL	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL ERYTHEMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL FISSURE	n/a	1783	100,0	15	0,8	1822	100,0	11	0,6	1,40		Algorithm converged.	0,64	3,05	0,002		Algorithm converged.	-0,003	0,008	1,39		Algorithm converged.	0,64	3,03	0,4016		0,72		Algorithm converged.	0,33	1,56
	ANAL FISTULA	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	ANAL HAEMORRHAGE	n/a	1783	100,0	10	0,6	1822	100,0	12	0,7	0,85		Algorithm converged.	0,37	1,97	-0,001		Algorithm converged.	-0,006	0,004	0,85		Algorithm converged.	0,37	1,97	0,7066		1,17		Algorithm converged.	0,51	2,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INCONTINENCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL INFLAMMATION	n/a	1783	100,0	8	0,4	1822	100,0	7	0,4	1,17		Algorithm converged.	0,42	3,23	0,001		Algorithm converged.	-0,004	0,005	1,17		Algorithm converged.	0,42	3,21	0,7638		0,86		Algorithm converged.	0,31	2,36
	ANAL PRURITUS	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,005	0,001	0,34		Algorithm converged.	0,07	1,69	0,1868		2,94		Algorithm converged.	0,59	14,53
	ANAL SKIN TAGS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	ANGULAR CHEILITIS	n/a	1783	100,0	18	1,0	1822	100,0	14	0,8	1,32		Algorithm converged.	0,65	2,66	0,002		Algorithm converged.	-0,004	0,009		1,31		Algorithm converged.	0,66	2,63	0,4417			0,76		Algorithm converged.	0,38	1,53	
	ANORECTAL DISCOMFORT	n/a	1783	100,0	7	0,4	1822	100,0	4	0,2	1,79		Algorithm converged.	0,52	6,13	0,002		Algorithm converged.	-0,002	0,005		1,79		Algorithm converged.	0,52	6,10	0,3531			0,56		Algorithm converged.	0,16	1,91	
	ANORECTAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	APHTHOUS ULCER	n/a	1783	100,0	26	1,5	1822	100,0	21	1,2	1,27		Algorithm converged.	0,71	2,26	0,003		Algorithm converged.	-0,004	0,010		1,27		Algorithm converged.	0,71	2,24	0,4197			0,79		Algorithm converged.	0,45	1,40	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APTYALISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASCITES	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREATH ODOUR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHANGE OF BOWEL HABIT	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHAPPED LIPS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	CHEILITIS	n/a	1783	100,0	4	0,2	1822	100,0	6	0,3	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,004	0,002		0,68		Algorithm converged.	0,19	2,41	0,5516		1,47		Algorithm converged.	0,41	5,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHRONIC GASTRITIS	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	COLITIS	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	COLITIS ISCHAEMIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONSTIPATION	n/a	1783	100,0	506	28,4	1822	100,0	548	30,1	0,92		Algorithm converged.	0,80	1,06	-0,017		Algorithm converged.	-0,047	0,013	0,94		Algorithm converged.	0,85	1,04	0,2627		1,06		Algorithm converged.	0,96	1,17
	DENTAL CARIES	n/a	1783	100,0	10	0,6	1822	100,0	10	0,5	1,02		Algorithm converged.	0,42	2,46	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,43	2,45	0,9613		0,98		Algorithm converged.	0,41	2,35
	DIARRHOEA	n/a	1783	100,0	1255	70,4	1822	100,0	824	45,2	2,88		Algorithm converged.	2,51	3,30	0,252		Algorithm converged.	0,220	0,283	1,56		Algorithm converged.	1,47	1,65	<.0001		0,64		Algorithm converged.	0,61	0,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA HAEMORRHAGIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULUM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULUM INTESTINAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DIVERTICULUM OESOPHAGEAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	DRY MOUTH	n/a	1783	100,0	107	6,0	1822	100,0	102	5,6	1,08		Algorithm converged.	0,81	1,42	0,004		Algorithm converged.	-0,011	0,019	1,07		Algorithm converged.	0,82	1,39	0,6049		0,93		Algorithm converged.	0,72	1,21	
	DUODENAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	DUODENAL ULCER	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DUODENITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DYSCHEZIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPEPSIA	n/a	1783	100,0	243	13,6	1822	100,0	246	13,5	1,01		Algorithm converged.	0,84	1,22	0,001		Algorithm converged.	-0,021	0,024	1,01		Algorithm converged.	0,86	1,19	0,9113		0,99		Algorithm converged.	0,84	1,17
	DYSPHAGIA	n/a	1783	100,0	56	3,1	1822	100,0	44	2,4	1,31		Algorithm converged.	0,88	1,96	0,007		Algorithm converged.	-0,003	0,018	1,30		Algorithm converged.	0,88	1,92	0,1859		0,77		Algorithm converged.	0,52	1,13
	ENTERITIS	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01
	ENTEROCOLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	EPIGASTRIC DISCOMFORT	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	ERUCTATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	FAECALOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FAECES SOFT	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FLATULENCE	n/a	1783	100,0	33	1,9	1822	100,0	32	1,8	1,05		Algorithm converged.	0,65	1,72	0,001		Algorithm converged.	-0,008	0,010	1,05		Algorithm converged.	0,65	1,71	0,8312		0,95		Algorithm converged.	0,59	1,54
	FOOD POISONING	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FREQUENT BOWEL MOVEMENTS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	FUNCTIONAL GASTROINTESTINAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC DILATATION	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	GASTRIC DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC MUCOSA ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC POLYPS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTRIC ULCER	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	n/a	1783	100,0	44	2,5	1822	100,0	31	1,7	1,46		Algorithm converged.	0,92	2,33	0,008		Algorithm converged.	-0,002	0,017		1,45		Algorithm converged.	0,92	2,29	0,1092		0,69		Algorithm converged.	0,44	1,09
	GASTRITIS EROSIVE	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	GASTROINTESTINAL DISORDER	n/a	1783	100,0	12	0,7	1822	100,0	14	0,8	0,88		Algorithm converged.	0,40	1,90	-0,001		Algorithm converged.	-0,006	0,005		0,88		Algorithm converged.	0,41	1,89	0,7353		1,14		Algorithm converged.	0,53	2,46
	GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL INFLAMMATION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL MOTILITY DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	GASTROINTESTINAL MUCOSAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	GASTROINTESTINAL PAIN	n/a	1783	100,0	19	1,1	1822	100,0	9	0,5	2,17		Algorithm converged.	0,98	4,81	0,006		Algorithm converged.	0,000	0,011		2,16		Algorithm converged.	0,98	4,76	0,0566			0,46		Algorithm converged.	0,21	1,02	
	GASTROINTESTINAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL SOUNDS ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL TOXICITY	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	GASTROOESOPHAGEAL REFLUX DISEASE	n/a	1783	100,0	90	5,0	1822	100,0	82	4,5	1,13		Algorithm converged.	0,83	1,53	0,005		Algorithm converged.	-0,008	0,019	1,12		Algorithm converged.	0,84	1,50	0,4413		0,89		Algorithm converged.	0,67	1,19
	GINGIVAL ATROPHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	GINGIVAL BLEEDING	n/a	1783	100,0	15	0,8	1822	100,0	12	0,7	1,28		Algorithm converged.	0,60	2,74	0,002		Algorithm converged.	-0,004	0,007		1,28		Algorithm converged.	0,60	2,72	0,5258		0,78		Algorithm converged.	0,37	1,67	
	GINGIVAL PAIN	n/a	1783	100,0	16	0,9	1822	100,0	17	0,9	0,96		Algorithm converged.	0,48	1,91	0,000		Algorithm converged.	-0,007	0,006		0,96		Algorithm converged.	0,49	1,90	0,9105		1,04		Algorithm converged.	0,53	2,05	
	GINGIVAL SWELLING	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84	
	GINGIVAL ULCERATION	n/a	1783	100,0	3	0,2	1822	100,0	9	0,5	0,34		Algorithm converged.	0,09	1,26	-0,003		Algorithm converged.	-0,007	0,000		0,34		Algorithm converged.	0,09	1,26	0,1058		2,94		Algorithm converged.	0,80	10,83	
	GLOSSITIS	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003		0,88		Algorithm converged.	0,29	2,60	0,8114		1,14		Algorithm converged.	0,38	3,39	
	GLOSSODYNIA	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005		2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95	
	HAEMATOCHEZIA	n/a	1783	100,0	10	0,6	1822	100,0	10	0,5	1,02		Algorithm converged.	0,42	2,46	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,43	2,45	0,9613		0,98		Algorithm converged.	0,41	2,35	
	HAEMORRHOIDAL HAEMORRHAGE	n/a	1783	100,0	23	1,3	1822	100,0	16	0,9	1,48		Algorithm converged.	0,78	2,80	0,004		Algorithm converged.	-0,003	0,011		1,47		Algorithm converged.	0,78	2,77	0,2350		0,68		Algorithm converged.	0,36	1,28	
	HAEMORRHOIDS	n/a	1783	100,0	134	7,5	1822	100,0	96	5,3	1,46		Algorithm converged.	1,11	1,92	0,022		Algorithm converged.	0,006	0,038		1,43		Algorithm converged.	1,11	1,84	0,0061		0,70		Algorithm converged.	0,54	0,90	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HIATUS HERNIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERAESTHESIA TEETH	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	HYPERCHLORHYDRIA	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	HYPOAESTHESIA ORAL	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	ILEUS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IMPAIRED GASTRIC EMPTYING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGUINAL HERNIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	INTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL ISCHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTESTINAL OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTUSSUSCEPTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IRRITABLE BOWEL SYNDROME	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	LARGE INTESTINAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	LARGE INTESTINE POLYP	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	LIP DRY	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57	
	LIP EROSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	LIP OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIP PAIN	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	LIP SWELLING	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	LIP ULCERATION	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	LOOSE TOOTH	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MELAENA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	MOUTH HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	MOUTH ULCERATION	n/a	1783	100,0	53	3,0	1822	100,0	59	3,2	0,92		Algorithm converged.	0,63	1,33	-0,003		Algorithm converged.	-0,014	0,009	0,92		Algorithm converged.	0,64	1,32	0,6459		1,09		Algorithm converged.	0,76	1,57	
	NAUSEA	n/a	1783	100,0	1233	69,2	1822	100,0	1187	65,1	1,20		Algorithm converged.	1,04	1,38	0,040		Algorithm converged.	0,009	0,071	1,06		Algorithm converged.	1,01	1,11	0,0105		0,94		Algorithm converged.	0,90	0,99	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NONINFECTIVE GINGIVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ODYNOPHAGIA	n/a	1783	100,0	13	0,7	1822	100,0	12	0,7	1,11		Algorithm converged.	0,50	2,43	0,001		Algorithm converged.	-0,005	0,006	1,11		Algorithm converged.	0,51	2,42	0,7988		0,90		Algorithm converged.	0,41	1,97
	OEDEMA MOUTH	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OESOPHAGEAL DISCOMFORT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OESOPHAGEAL PAIN	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	OESOPHAGEAL SPASM	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	OESOPHAGEAL STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OESOPHAGITIS	n/a	1783	100,0	24	1,3	1822	100,0	17	0,9	1,45		Algorithm converged.	0,78	2,71	0,004		Algorithm converged.	-0,003	0,011		1,44		Algorithm converged.	0,78	2,68	0,2450			0,69		Algorithm converged.	0,37	1,29
	ORAL DISCOMFORT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	ORAL DISORDER	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593			0,49		Algorithm converged.	0,04	5,39
	ORAL DYSAESTHESIA	n/a	1783	100,0	3	0,2	1822	100,0	9	0,5	0,34		Algorithm converged.	0,09	1,26	-0,003		Algorithm converged.	-0,007	0,000		0,34		Algorithm converged.	0,09	1,26	0,1058			2,94		Algorithm converged.	0,80	10,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL LICHEN PLANUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL MUCOSA HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL MUCOSAL BLISTERING	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL MUCOSAL ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL MUCOSAL ERYTHEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL PAIN	n/a	1783	100,0	27	1,5	1822	100,0	34	1,9	0,81		Algorithm converged.	0,49	1,35	-0,004		Algorithm converged.	-0,012	0,005	0,81		Algorithm converged.	0,49	1,34	0,4138		1,23		Algorithm converged.	0,75	2,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OVERFLOW DIARRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PANCREATIC DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	PANCREATITIS	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	PANCREATITIS ACUTE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARAESTHESIA ORAL	n/a	1783	100,0	7	0,4	1822	100,0	4	0,2	1,79		Algorithm converged.	0,52	6,13	0,002		Algorithm converged.	-0,002	0,005	1,79		Algorithm converged.	0,52	6,10	0,3531		0,56		Algorithm converged.	0,16	1,91
	PAROTID GLAND ENLARGEMENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PEPTIC ULCER	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	PERIODONTAL DISEASE	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84
	PROCTALGIA	n/a	1783	100,0	11	0,6	1822	100,0	6	0,3	1,88		Algorithm converged.	0,69	5,09	0,003		Algorithm converged.	-0,002	0,007	1,87		Algorithm converged.	0,69	5,05	0,2151		0,53		Algorithm converged.	0,20	1,44
	PROCTITIS	n/a	1783	100,0	8	0,4	1822	100,0	4	0,2	2,05		Algorithm converged.	0,62	6,81	0,002		Algorithm converged.	-0,001	0,006	2,04		Algorithm converged.	0,62	6,77	0,2424		0,49		Algorithm converged.	0,15	1,62
	RECTAL HAEMORRHAGE	n/a	1783	100,0	24	1,3	1822	100,0	17	0,9	1,45		Algorithm converged.	0,78	2,71	0,004		Algorithm converged.	-0,003	0,011	1,44		Algorithm converged.	0,78	2,68	0,2450		0,69		Algorithm converged.	0,37	1,29

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL TENESMUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	REFLUX GASTRITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	RETCHING	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SALIVARY GLAND PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SALIVARY HYPERSECRETION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004		2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	SMALL INTESTINAL OBSTRUCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	n/a	1783	100,0	515	28,9	1822	100,0	430	23,6	1,31		Algorithm converged.	1,13	1,53	0,053		Algorithm converged.	0,024	0,082		1,22		Algorithm converged.	1,10	1,37	0,0003		0,82		Algorithm converged.	0,73	0,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRAWBERRY TONGUE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBILEUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SWOLLEN TONGUE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONGUE BLISTERING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONGUE COATED	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003		3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	TONGUE DISCOLOURATION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TONGUE DISCOMFORT	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	TONGUE ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONGUE PRURITUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TONGUE ULCERATION	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	TOOTH DEVELOPMENT DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH DISCOLOURATION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOOTH IMPACTED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TOOTH LOSS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOOTHACHE	n/a	1783	100,0	38	2,1	1822	100,0	43	2,4	0,90		Algorithm converged.	0,58	1,40	-0,002		Algorithm converged.	-0,012	0,007	0,90		Algorithm converged.	0,59	1,39	0,6432		1,11		Algorithm converged.	0,72	1,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UMBILICAL HERNIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	VOMITING	n/a	1783	100,0	605	33,9	1822	100,0	566	31,1	1,14		Algorithm converged.	0,99	1,31	0,029		Algorithm converged.	-0,002	0,059	1,09		Algorithm converged.	0,99	1,20	0,0663		0,92		Algorithm converged.	0,83	1,01
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	1500	84,1	1822	100,0	1476	81,0	1,24		Algorithm converged.	1,05	1,48	0,031		Algorithm converged.	0,006	0,056	1,04		Algorithm converged.	1,01	1,07	0,0136		0,96		Algorithm converged.	0,93	0,99
	ADVERSE DRUG REACTION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPLICATION SITE RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASTHENIA	n/a	1783	100,0	380	21,3	1822	100,0	367	20,1	1,07		Algorithm converged.	0,91	1,26	0,012		Algorithm converged.	-0,015	0,038		1,06		Algorithm converged.	0,93	1,20	0,3864		0,95		Algorithm converged.	0,83	1,07
	AXILLARY PAIN	n/a	1783	100,0	30	1,7	1822	100,0	22	1,2	1,40		Algorithm converged.	0,80	2,44	0,005		Algorithm converged.	-0,003	0,013		1,39		Algorithm converged.	0,81	2,41	0,2339		0,72		Algorithm converged.	0,42	1,24
	CATHETER SITE BRUISE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CATHETER SITE ERYTHEMA	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003		0,85		Algorithm converged.	0,26	2,79	0,7904			1,17		Algorithm converged.	0,36	3,84	
	CATHETER SITE INFLAMMATION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004		2,04		Algorithm converged.	0,37	11,14	0,4088			0,49		Algorithm converged.	0,09	2,67	
	CATHETER SITE IRRITATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE PAIN	n/a	1783	100,0	14	0,8	1822	100,0	17	0,9	0,84		Algorithm converged.	0,41	1,71	-0,001		Algorithm converged.	-0,008	0,005	0,84		Algorithm converged.	0,42	1,70	0,6312		1,19		Algorithm converged.	0,59	2,40
	CATHETER SITE PRURITUS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CATHETER SITE RASH	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	CHEST DISCOMFORT	n/a	1783	100,0	26	1,5	1822	100,0	33	1,8	0,80		Algorithm converged.	0,48	1,35	-0,004		Algorithm converged.	-0,012	0,005	0,81		Algorithm converged.	0,48	1,34	0,4046		1,24		Algorithm converged.	0,75	2,07
	CHEST PAIN	n/a	1783	100,0	51	2,9	1822	100,0	56	3,1	0,93		Algorithm converged.	0,63	1,36	-0,002		Algorithm converged.	-0,013	0,009	0,93		Algorithm converged.	0,64	1,35	0,7062		1,07		Algorithm converged.	0,74	1,56
	CHILLS	n/a	1783	100,0	70	3,9	1822	100,0	77	4,2	0,93		Algorithm converged.	0,67	1,29	-0,003		Algorithm converged.	-0,016	0,010	0,93		Algorithm converged.	0,68	1,28	0,6488		1,08		Algorithm converged.	0,78	1,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COMPLICATION ASSOCIATED WITH DEVICE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CREPITATIONS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CRYING	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CYST	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	CYST RUPTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED THROMBOSIS	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3	0,51		Algorithm converged.	0,13	2,04	-0,002		Algorithm converged.	-0,005	0,002	0,51		Algorithm converged.	0,13	2,04	0,3417		1,96		Algorithm converged.	0,49	7,81
	DISCOMFORT	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENANTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXERCISE TOLERANCE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTRAVASATION	n/a	1783	100,0	5	0,3	1822	100,0	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,30	3,52	0,9727		0,98		Algorithm converged.	0,28	3,37
	FACE OEDEMA	n/a	1783	100,0	24	1,3	1822	100,0	33	1,8	0,74		Algorithm converged.	0,44	1,26	-0,005		Algorithm converged.	-0,013	0,003		0,74		Algorithm converged.	0,44	1,25	0,2648		1,35		Algorithm converged.	0,80	2,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACIAL PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	FAT NECROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FATIGUE	n/a	1783	100,0	866	48,6	1822	100,0	806	44,2	1,19		Algorithm converged.	1,04	1,36	0,043		Algorithm converged.	0,011	0,076	1,10		Algorithm converged.	1,02	1,18	0,0092		0,91		Algorithm converged.	0,85	0,98
	FEELING ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FEELING COLD	n/a	1783	100,0	9	0,5	1822	100,0	8	0,4	1,15		Algorithm converged.	0,44	2,99	0,001		Algorithm converged.	-0,004	0,005	1,15		Algorithm converged.	0,44	2,97	0,7737		0,87		Algorithm converged.	0,34	2,25
	FEELING HOT	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	FEELING JITTERY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FEELING OF BODY TEMPERATURE CHANGE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FIBROSIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	FOREIGN BODY REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	GAIT DISTURBANCE	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	GENERALISED OEDEMA	n/a	1783	100,0	7	0,4	1822	100,0	11	0,6	0,65		Algorithm converged.	0,25	1,68	-0,002		Algorithm converged.	-0,007	0,002	0,65		Algorithm converged.	0,25	1,67	0,3723		1,54		Algorithm converged.	0,60	3,96
	HUNGER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPYREXIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHERMIA	n/a	1783	100,0	6	0,3	1822	100,0	11	0,6	0,56		Algorithm converged.	0,21	1,51	-0,003		Algorithm converged.	-0,007	0,002	0,56		Algorithm converged.	0,21	1,50	0,2484		1,79		Algorithm converged.	0,66	4,84
	HYPOTHERMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ILL-DEFINED DISORDER	n/a	1783	100,0	15	0,8	1822	100,0	16	0,9	0,96		Algorithm converged.	0,47	1,94	0,000		Algorithm converged.	-0,006	0,006	0,96		Algorithm converged.	0,48	1,93	0,9046		1,04		Algorithm converged.	0,52	2,10

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ILLNESS	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	IMPAIRED HEALING	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	IMPLANT SITE INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INDURATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	INFLAMMATION	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	INFLUENZA LIKE ILLNESS	n/a	1783	100,0	100	5,6	1822	100,0	91	5,0	1,13		Algorithm converged.	0,84	1,51	0,006		Algorithm converged.	-0,008	0,021	1,12		Algorithm converged.	0,85	1,48	0,4109		0,89		Algorithm converged.	0,68	1,17
	INFUSION SITE EXTRAVASATION	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE BRUISING	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE DISCOMFORT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE EXTRAVASATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE HYPERSENSITIVITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INJECTION SITE PAIN	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INJECTION SITE PHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE PRURITUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE RASH	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE REACTION	n/a	1783	100,0	10	0,6	1822	100,0	6	0,3	1,71		Algorithm converged.	0,62	4,71	0,002		Algorithm converged.	-0,002	0,007	1,70		Algorithm converged.	0,62	4,68	0,3015		0,59		Algorithm converged.	0,21	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOCALISED OEDEMA	n/a	1783	100,0	16	0,9	1822	100,0	14	0,8	1,17		Algorithm converged.	0,57	2,40	0,001		Algorithm converged.	-0,005	0,007		1,17		Algorithm converged.	0,57	2,39	0,6703		0,86		Algorithm converged.	0,42	1,75
	MALAISE	n/a	1783	100,0	55	3,1	1822	100,0	73	4,0	0,76		Algorithm converged.	0,53	1,09	-0,009		Algorithm converged.	-0,021	0,003		0,77		Algorithm converged.	0,55	1,09	0,1360		1,30		Algorithm converged.	0,92	1,83
	MASS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004		4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	MEDICAL DEVICE PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	METAPLASIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUCOSAL DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	MUCOSAL DRYNESS	n/a	1783	100,0	32	1,8	1822	100,0	22	1,2	1,50		Algorithm converged.	0,87	2,58	0,006		Algorithm converged.	-0,002	0,014		1,49		Algorithm converged.	0,87	2,55	0,1494		0,67		Algorithm converged.	0,39	1,15
	MUCOSAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk											
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	MUCOSAL INFLAMMATION	n/a	1783	100,0	405	22,7	1822	100,0	315	17,3	1,41		Algorithm converged.	1,19	1,66	0,054		Algorithm converged.	0,028	0,080	1,31		Algorithm converged.	1,15	1,50	<.0001		0,76		Algorithm converged.	0,67	0,87						
	MUCOSAL TOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	MUCOSAL ULCERATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk									Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NODULE	n/a	1783	100,0	6	0,3	1822	100,0	2	0,1	3,07		Algorithm converged.	0,62	15,24	0,002		Algorithm converged.	-0,001	0,005		3,07		Algorithm converged.	0,62	15,17	0,1697			0,33		Algorithm converged.	0,07	1,61
	NON-CARDIAC CHEST PAIN	n/a	1783	100,0	7	0,4	1822	100,0	15	0,8	0,47		Algorithm converged.	0,19	1,17	-0,004		Algorithm converged.	-0,009	0,001		0,48		Algorithm converged.	0,19	1,17	0,1048			2,10		Algorithm converged.	0,86	5,13
	OEDEMA	n/a	1783	100,0	111	6,2	1822	100,0	117	6,4	0,97		Algorithm converged.	0,74	1,27	-0,002		Algorithm converged.	-0,018	0,014		0,97		Algorithm converged.	0,75	1,25	0,8090			1,03		Algorithm converged.	0,80	1,33
	OEDEMA PERIPHERAL	n/a	1783	100,0	304	17,0	1822	100,0	368	20,2	0,81		Algorithm converged.	0,69	0,96	-0,031		Algorithm converged.	-0,057	-0,006		0,84		Algorithm converged.	0,74	0,97	0,0155			1,18		Algorithm converged.	1,03	1,36
	PAIN	n/a	1783	100,0	126	7,1	1822	100,0	114	6,3	1,14		Algorithm converged.	0,88	1,48	0,008		Algorithm converged.	-0,008	0,024		1,13		Algorithm converged.	0,88	1,44	0,3298			0,89		Algorithm converged.	0,69	1,13
	PERIPHERAL SWELLING	n/a	1783	100,0	31	1,7	1822	100,0	36	2,0	0,88		Algorithm converged.	0,54	1,43	-0,002		Algorithm converged.	-0,011	0,006		0,88		Algorithm converged.	0,55	1,42	0,5983			1,14		Algorithm converged.	0,71	1,83
	PUNCTURE SITE PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	PYREXIA	n/a	1783	100,0	359	20,1	1822	100,0	346	19,0	1,08		Algorithm converged.	0,91	1,27	0,011		Algorithm converged.	-0,014	0,037		1,06		Algorithm converged.	0,93	1,21	0,3865			0,94		Algorithm converged.	0,83	1,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCAR INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SECRETION DISCHARGE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	SENSATION OF FOREIGN BODY	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	SUPRAPUBIC PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SWELLING	n/a	1783	100,0	9	0,5	1822	100,0	6	0,3	1,54		Algorithm converged.	0,55	4,32	0,002		Algorithm converged.	-0,002	0,006	1,53		Algorithm converged.	0,55	4,30	0,4168		0,65		Algorithm converged.	0,23	1,83
	SWELLING FACE	n/a	1783	100,0	11	0,6	1822	100,0	8	0,4	1,41		Algorithm converged.	0,56	3,51	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,48	0,4631		0,71		Algorithm converged.	0,29	1,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TEMPERATURE INTOLERANCE	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TEMPERATURE REGULATION DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDERNESS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THIRST	n/a	1783	100,0	9	0,5	1822	100,0	6	0,3	1,54		Algorithm converged.	0,55	4,32	0,002		Algorithm converged.	-0,002	0,006		1,53		Algorithm converged.	0,55	4,30	0,4168		0,65		Algorithm converged.	0,23	1,83
	ULCER	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002		0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	UNEVALUABLE EVENT	n/a	1783	100,0	10	0,6	1822	100,0	3	0,2	3,42		Algorithm converged.	0,94	12,45	0,004		Algorithm converged.	0,000	0,008		3,41		Algorithm converged.	0,94	12,36	0,0623		0,29		Algorithm converged.	0,08	1,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR DEVICE OCCLUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VESSEL PUNCTURE SITE BRUISE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	XEROSIS	n/a	1783	100,0	11	0,6	1822	100,0	4	0,2	2,82		Algorithm converged.	0,90	8,88	0,004		Algorithm converged.	0,000	0,008	2,81		Algorithm converged.	0,90	8,81	0,0763		0,36		Algorithm converged.	0,11	1,12
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	54	3,0	1822	100,0	60	3,3	0,92		Algorithm converged.	0,63	1,33	-0,003		Algorithm converged.	-0,014	0,009	0,92		Algorithm converged.	0,64	1,32	0,6502		1,09		Algorithm converged.	0,76	1,56

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BILIARY COLIC	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	CHOLANGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	CHOLECYSTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS ACUTE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLECYSTITIS CHRONIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHOLELITHIASIS	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	CHOLESTASIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG-INDUCED LIVER INJURY	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GALLBLADDER POLYP	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYST	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	HEPATIC CYTOLYSIS	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	HEPATIC FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FUNCTION ABNORMAL	n/a	1783	100,0	13	0,7	1822	100,0	22	1,2	0,60		Algorithm converged.	0,30	1,20	-0,005		Algorithm converged.	-0,011	0,002	0,60		Algorithm converged.	0,31	1,19	0,1474		1,66		Algorithm converged.	0,84	3,28
	HEPATIC PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	HEPATIC STEATOSIS	n/a	1783	100,0	10	0,6	1822	100,0	10	0,5	1,02		Algorithm converged.	0,42	2,46	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,43	2,45	0,9613		0,98		Algorithm converged.	0,41	2,35
	HEPATITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HEPATITIS ACUTE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	HEPATOBILIARY DISEASE	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01	
	HEPATOTOXICITY	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27	
	HYPERBILIRUBINAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRANSAMINASAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIVER DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIVER INJURY	n/a	1783	100,0	5	0,3	1822	100,0	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,30	3,52	0,9727		0,98		Algorithm converged.	0,28	3,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OCULAR ICTERUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	99	5,6	1822	100,0	80	4,4	1,28		Algorithm converged.	0,95	1,73	0,012		Algorithm converged.	-0,003	0,026	1,26		Algorithm converged.	0,95	1,69	0,1093		0,79		Algorithm converged.	0,59	1,05
	ALLERGIC OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALLERGY TO ANIMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAPHYLACTIC REACTION	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED IMMUNE RESPONSIVENESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	23	1,3	1822	100,0	11	0,6	2,15		Algorithm converged.	1,05	4,43	0,007		Algorithm converged.	0,001	0,013	2,14		Algorithm converged.	1,04	4,37	0,0376		0,47		Algorithm converged.	0,23	0,96
	FOOD ALLERGY	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPERSENSITIVITY	n/a	1783	100,0	53	3,0	1822	100,0	52	2,9	1,04		Algorithm converged.	0,71	1,54	0,001		Algorithm converged.	-0,010	0,012		1,04		Algorithm converged.	0,71	1,52	0,8325			0,96		Algorithm converged.	0,66	1,40	
	IMMUNE SYSTEM DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	INFUSION RELATED HYPERSENSITIVITY REACTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827			0,98		Algorithm converged.	0,14	6,94	
	SEASONAL ALLERGY	n/a	1783	100,0	16	0,9	1822	100,0	9	0,5	1,82		Algorithm converged.	0,80	4,14	0,004		Algorithm converged.	-0,001	0,009		1,82		Algorithm converged.	0,80	4,10	0,1506			0,55		Algorithm converged.	0,24	1,24	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERUM SICKNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	1084	60,8	1822	100,0	1056	58,0	1,12		Algorithm converged.	0,98	1,28	0,028		Algorithm converged.	-0,004	0,060	1,05		Algorithm converged.	0,99	1,11	0,0828		0,95		Algorithm converged.	0,90	1,01
	ABDOMINAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001		0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	ABSCESS JAW	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS LIMB	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ABSCESS ORAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ACARODERMATITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACTINOMYCOSIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE HEPATITIS B	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE SINUSITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADENOVIRAL CONJUNCTIVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL ABSCESS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ANAL FUNGAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS PERFORATED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ARTHRITIS INFECTIVE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ASCARIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	BACTERIAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	BACTERIAL VAGINOSIS	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL VULVOVAGINITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BARTHOLINITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BETA HAEMOLYTIC STREPTOCOCCAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BODY TINEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BOTRYOMYCOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST ABSCESS	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	BREAST CELLULITIS	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,005	0,001	0,34		Algorithm converged.	0,07	1,69	0,1868		2,94		Algorithm converged.	0,59	14,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BRONCHIOLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	BRONCHITIS	n/a	1783	100,0	57	3,2	1822	100,0	73	4,0	0,79		Algorithm converged.	0,56	1,13	-0,008		Algorithm converged.	-0,020	0,004		0,80		Algorithm converged.	0,57	1,12	0,1934			1,25		Algorithm converged.	0,89	1,76	
	BRONCHITIS VIRAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BULLOUS IMPETIGO	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BURN INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CAMPYLOBACTER INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	CANDIDA INFECTION	n/a	1783	100,0	24	1,3	1822	100,0	20	1,1	1,23		Algorithm converged.	0,68	2,23	0,002		Algorithm converged.	-0,005	0,010	1,23		Algorithm converged.	0,68	2,21	0,4979		0,82		Algorithm converged.	0,45	1,47	
	CARBUNCLE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3	0,51		Algorithm converged.	0,13	2,04	-0,002		Algorithm converged.	-0,005	0,002	0,51		Algorithm converged.	0,13	2,04	0,3417		1,96		Algorithm converged.	0,49	7,81
	CATHETER SITE PUSTULE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CELLULITIS	n/a	1783	100,0	34	1,9	1822	100,0	33	1,8	1,05		Algorithm converged.	0,65	1,71	0,001		Algorithm converged.	-0,008	0,010	1,05		Algorithm converged.	0,66	1,69	0,8316		0,95		Algorithm converged.	0,59	1,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CELLULITIS ORBITAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CERVICITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEST WALL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHRONIC SINUSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CHRONIC TONSILLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CLOSTRIDIUM COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE INFECTION	n/a	1783	100,0	6	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONJUNCTIVITIS	n/a	1783	100,0	110	6,2	1822	100,0	93	5,1	1,22		Algorithm converged.	0,92	1,62	0,011		Algorithm converged.	-0,004	0,026	1,21		Algorithm converged.	0,92	1,58	0,1662		0,83		Algorithm converged.	0,63	1,08
	CONJUNCTIVITIS VIRAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CYSTITIS	n/a	1783	100,0	63	3,5	1822	100,0	48	2,6	1,35		Algorithm converged.	0,92	1,98	0,009		Algorithm converged.	-0,002	0,020	1,34		Algorithm converged.	0,93	1,94	0,1197		0,75		Algorithm converged.	0,52	1,08
	DENGUE FEVER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS INFECTED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATOPHYTOSIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED INFECTION	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	DIENTAMOEBA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS	n/a	1783	100,0	4	0,2	1822	100,0	7	0,4	0,58		Algorithm converged.	0,17	1,99	-0,002		Algorithm converged.	-0,005	0,002	0,58		Algorithm converged.	0,17	1,99	0,3900		1,71		Algorithm converged.	0,50	5,84
	DIVERTICULITIS INTESTINAL PERFORATED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EAR INFECTION	n/a	1783	100,0	6	0,3	1822	100,0	12	0,7	0,51		Algorithm converged.	0,19	1,36	-0,003		Algorithm converged.	-0,008	0,001	0,51		Algorithm converged.	0,19	1,36	0,1783		1,96		Algorithm converged.	0,74	5,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ENDOCARDITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	ENTERITIS INFECTIOUS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROBIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ENTEROCOLITIS INFECTIOUS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	n/a	1783	100,0	16	0,9	1822	100,0	6	0,3	2,74		Algorithm converged.	1,07	7,02	0,006		Algorithm converged.	0,001	0,011	2,72		Algorithm converged.	1,07	6,95	0,0358		0,37		Algorithm converged.	0,14	0,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHERICHIA INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ESCHERICHIA URINARY TRACT INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYE INFECTION	n/a	1783	100,0	11	0,6	1822	100,0	18	1,0	0,62		Algorithm converged.	0,29	1,32	-0,004		Algorithm converged.	-0,010	0,002	0,62		Algorithm converged.	0,30	1,32	0,2168		1,60		Algorithm converged.	0,76	3,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID FOLLICULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYELID INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOLLICULITIS	n/a	1783	100,0	26	1,5	1822	100,0	14	0,8	1,91		Algorithm converged.	0,99	3,67	0,007		Algorithm converged.	0,000	0,014	1,90		Algorithm converged.	0,99	3,62	0,0521		0,53		Algorithm converged.	0,28	1,01
	FUNGAL INFECTION	n/a	1783	100,0	12	0,7	1822	100,0	10	0,5	1,23		Algorithm converged.	0,53	2,85	0,001		Algorithm converged.	-0,004	0,006	1,23		Algorithm converged.	0,53	2,83	0,6328		0,82		Algorithm converged.	0,35	1,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	FUNGAL OESOPHAGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	FUNGAL PHARYNGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	FUNGAL SKIN INFECTION	n/a	1783	100,0	11	0,6	1822	100,0	9	0,5	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,006		1,25		Algorithm converged.	0,52	3,01	0,6199			0,80		Algorithm converged.	0,33	1,93	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FURUNCLE	n/a	1783	100,0	5	0,3	1822	100,0	11	0,6	0,46		Algorithm converged.	0,16	1,34	-0,003		Algorithm converged.	-0,008	0,001	0,46		Algorithm converged.	0,16	1,33	0,1543		2,15		Algorithm converged.	0,75	6,18
	GASTRIC INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROENTERITIS	n/a	1783	100,0	33	1,9	1822	100,0	35	1,9	0,96		Algorithm converged.	0,60	1,56	-0,001		Algorithm converged.	-0,010	0,008	0,96		Algorithm converged.	0,60	1,54	0,8770		1,04		Algorithm converged.	0,65	1,66
	GASTROENTERITIS VIRAL	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL FUNGAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508507 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	GASTROINTESTINAL VIRAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	GENITAL HERPES	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	GENITAL HERPES SIMPLEX	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	GENITAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL INFECTION FEMALE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENITAL INFECTION FUNGAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	GENITOURINARY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GINGIVAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GINGIVITIS	n/a	1783	100,0	28	1,6	1822	100,0	30	1,6	0,95		Algorithm converged.	0,57	1,60	-0,001		Algorithm converged.	-0,009	0,007	0,95		Algorithm converged.	0,57	1,59	0,8558		1,05		Algorithm converged.	0,63	1,75
	GROIN ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HELICOBACTER INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	HEPATITIS B REACTIVATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES OPHTHALMIC	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES SIMPLEX	n/a	1783	100,0	7	0,4	1822	100,0	10	0,5	0,71		Algorithm converged.	0,27	1,88	-0,002		Algorithm converged.	-0,006	0,003	0,72		Algorithm converged.	0,27	1,88	0,4956		1,40		Algorithm converged.	0,53	3,66
	HERPES VIRUS INFECTION	n/a	1783	100,0	15	0,8	1822	100,0	10	0,5	1,54		Algorithm converged.	0,69	3,43	0,003		Algorithm converged.	-0,003	0,008	1,53		Algorithm converged.	0,69	3,40	0,2939		0,65		Algorithm converged.	0,29	1,45
	HERPES ZOSTER	n/a	1783	100,0	37	2,1	1822	100,0	50	2,7	0,75		Algorithm converged.	0,49	1,15	-0,007		Algorithm converged.	-0,017	0,003	0,76		Algorithm converged.	0,50	1,15	0,1922		1,32		Algorithm converged.	0,87	2,01
	HORDEOLUM	n/a	1783	100,0	16	0,9	1822	100,0	20	1,1	0,82		Algorithm converged.	0,42	1,58	-0,002		Algorithm converged.	-0,008	0,004	0,82		Algorithm converged.	0,43	1,57	0,5460		1,22		Algorithm converged.	0,64	2,35
	IMPETIGO	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE CELLULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED BITE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTED LYMPHOCELE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTION	n/a	1783	100,0	34	1,9	1822	100,0	27	1,5	1,29		Algorithm converged.	0,78	2,15	0,004		Algorithm converged.	-0,004	0,013	1,29		Algorithm converged.	0,78	2,12	0,3239		0,78		Algorithm converged.	0,47	1,28
	INFLUENZA	n/a	1783	100,0	45	2,5	1822	100,0	61	3,3	0,75		Algorithm converged.	0,51	1,10	-0,008		Algorithm converged.	-0,019	0,003	0,75		Algorithm converged.	0,52	1,10	0,1445		1,33		Algorithm converged.	0,91	1,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LABYRINTHITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LARYNGITIS	n/a	1783	100,0	12	0,7	1822	100,0	16	0,9	0,76		Algorithm converged.	0,36	1,62	-0,002		Algorithm converged.	-0,008	0,004	0,77		Algorithm converged.	0,36	1,62	0,4843		1,30		Algorithm converged.	0,62	2,75
	LARYNGOPHARYNGITIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	LIP INFECTION	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003	0,88		Algorithm converged.	0,29	2,60	0,8114		1,14		Algorithm converged.	0,38	3,39
	LOCALISED INFECTION	n/a	1783	100,0	18	1,0	1822	100,0	9	0,5	2,05		Algorithm converged.	0,92	4,59	0,005		Algorithm converged.	0,000	0,011	2,04		Algorithm converged.	0,92	4,54	0,0790		0,49		Algorithm converged.	0,22	1,09
	LOWER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	19	1,1	1822	100,0	15	0,8	1,30		Algorithm converged.	0,66	2,56	0,002		Algorithm converged.	-0,004	0,009	1,29		Algorithm converged.	0,66	2,54	0,4529		0,77		Algorithm converged.	0,39	1,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPH GLAND INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHANGITIS	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	MASTITIS	n/a	1783	100,0	22	1,2	1822	100,0	18	1,0	1,25		Algorithm converged.	0,67	2,34	0,002		Algorithm converged.	-0,004	0,009	1,25		Algorithm converged.	0,67	2,32	0,4818		0,80		Algorithm converged.	0,43	1,49
	MORAXELLA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MUCOSAL INFECTION	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002		0,64		Algorithm converged.	0,21	1,95	0,4308			1,57		Algorithm converged.	0,51	4,78	
	MUMPS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	MYCOBACTERIAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYRINGITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	NAIL BED INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	NAIL INFECTION	n/a	1783	100,0	23	1,3	1822	100,0	21	1,2	1,12		Algorithm converged.	0,62	2,03	0,001		Algorithm converged.	-0,006	0,009	1,12		Algorithm converged.	0,62	2,01	0,7074		0,89		Algorithm converged.	0,50	1,61
	NASAL HERPES	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	NASAL VESTIBULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASOPHARYNGITIS	n/a	1783	100,0	234	13,1	1822	100,0	214	11,7	1,14		Algorithm converged.	0,93	1,38	0,014		Algorithm converged.	-0,008	0,035	1,12		Algorithm converged.	0,94	1,33	0,2100		0,89		Algorithm converged.	0,75	1,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	n/a	1783	100,0	8	0,4	1822	100,0	3	0,2	2,73		Algorithm converged.	0,72	10,32	0,003		Algorithm converged.	-0,001	0,006		2,72		Algorithm converged.	0,72	10,25	0,1382		0,37		Algorithm converged.	0,10	1,38
	OESOPHAGEAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	OMPHALITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170561853 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	ONYCHOMYCOSIS	n/a	1783	100,0	11	0,6	1822	100,0	4	0,2	2,82		Algorithm converged.	0,90	8,88	0,004		Algorithm converged.	0,000	0,008	2,81		Algorithm converged.	0,90	8,81	0,0763		0,36		Algorithm converged.	0,11	1,12						
	ORAL CANDIDIASIS	n/a	1783	100,0	23	1,3	1822	100,0	34	1,9	0,69		Algorithm converged.	0,40	1,17	-0,006		Algorithm converged.	-0,014	0,002	0,69		Algorithm converged.	0,41	1,17	0,1682		1,45		Algorithm converged.	0,86	2,45						
	ORAL FUNGAL INFECTION	n/a	1783	100,0	9	0,5	1822	100,0	6	0,3	1,54		Algorithm converged.	0,55	4,32	0,002		Algorithm converged.	-0,002	0,006	1,53		Algorithm converged.	0,55	4,30	0,4168		0,65		Algorithm converged.	0,23	1,83						
	ORAL HERPES	n/a	1783	100,0	30	1,7	1822	100,0	32	1,8	0,96		Algorithm converged.	0,58	1,58	-0,001		Algorithm converged.	-0,009	0,008	0,96		Algorithm converged.	0,58	1,57	0,8648		1,04		Algorithm converged.	0,64	1,71						
	ORAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94						
	OROPHARYNGITIS FUNGAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS EXTERNA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OTITIS MEDIA	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3	0,51		Algorithm converged.	0,13	2,04	-0,002		Algorithm converged.	-0,005	0,002	0,51		Algorithm converged.	0,13	2,04	0,3417		1,96		Algorithm converged.	0,49	7,81
	OTITIS MEDIA ACUTE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	OTITIS MEDIA BACTERIAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLOMA VIRAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	n/a	1783	100,0	67	3,8	1822	100,0	40	2,2	1,74		Algorithm converged.	1,17	2,59	0,016		Algorithm converged.	0,005	0,027	1,71		Algorithm converged.	1,16	2,52	0,0064		0,58		Algorithm converged.	0,40	0,86
	PAROTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PELVIC INFLAMMATORY DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PERICORONITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004		4,09		Algorithm converged.	0,46	36,53	0,2077			0,24		Algorithm converged.	0,03	2,19	
	PERIODONTITIS	n/a	1783	100,0	11	0,6	1822	100,0	7	0,4	1,61		Algorithm converged.	0,62	4,16	0,002		Algorithm converged.	-0,002	0,007		1,61		Algorithm converged.	0,62	4,13	0,3261			0,62		Algorithm converged.	0,24	1,60	
	PERIPHERAL NERVE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERITONSILLAR ABSCESS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERITONSILLITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERTUSSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHARYNGITIS	n/a	1783	100,0	73	4,1	1822	100,0	68	3,7	1,10		Algorithm converged.	0,79	1,54	0,004		Algorithm converged.	-0,009	0,016	1,10		Algorithm converged.	0,79	1,52	0,5752		0,91		Algorithm converged.	0,66	1,26
	PHARYNGITIS BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGITIS STREPTOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHARYNGOTONSILLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PHLEBITIS INFECTIVE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PILONIDAL CYST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PLEURAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PNEUMOCYSTIS JIROVECII PNEUMONIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE				NE		Algorithm converged.	NE	NE	
	PNEUMONIA	n/a	1783	100,0	40	2,2	1822	100,0	35	1,9	1,17		Algorithm converged.	0,74	1,85	0,003		Algorithm converged.	-0,006	0,013		1,17		Algorithm converged.	0,75	1,83	0,4981				0,86		Algorithm converged.	0,55	1,34	
	PNEUMONIA ASPIRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE				NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMONIA CHLAMYDIAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA PNEUMOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	POST PROCEDURAL CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	POST PROCEDURAL INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003		3,07		Algorithm converged.	0,32	29,44	0,3318			0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	PSEUDOMEMBRANOUS COLITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	PSEUDOMONAS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834			1,96		Algorithm converged.	0,18	21,57
	PULMONARY TUBERCULOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	PULPITIS DENTAL	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593			0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PURULENT DISCHARGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	PUSTULE	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002		0,77		Algorithm converged.	0,17	3,42	0,7273			1,30		Algorithm converged.	0,29	5,82	
	PYELONEPHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS ACUTE	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYODERMA STREPTOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	RADIATION SITE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	RASH PUSTULAR	n/a	1783	100,0	18	1,0	1822	100,0	10	0,5	1,85		Algorithm converged.	0,85	4,01	0,005		Algorithm converged.	-0,001	0,010		1,84		Algorithm converged.	0,85	3,97	0,1210			0,54		Algorithm converged.	0,25	1,17	
	RECTAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	n/a	1783	100,0	24	1,3	1822	100,0	16	0,9	1,54		Algorithm converged.	0,82	2,91	0,005		Algorithm converged.	-0,002	0,012	1,53		Algorithm converged.	0,82	2,88	0,1834		0,65		Algorithm converged.	0,35	1,22
	RESPIRATORY TRACT INFECTION VIRAL	n/a	1783	100,0	10	0,6	1822	100,0	14	0,8	0,73		Algorithm converged.	0,32	1,64	-0,002		Algorithm converged.	-0,007	0,003	0,73		Algorithm converged.	0,33	1,64	0,4455		1,37		Algorithm converged.	0,61	3,08
	RHINITIS	n/a	1783	100,0	105	5,9	1822	100,0	81	4,4	1,34		Algorithm converged.	1,00	1,81	0,014		Algorithm converged.	0,000	0,029	1,32		Algorithm converged.	1,00	1,76	0,0510		0,75		Algorithm converged.	0,57	1,00
	RHINOVIRUS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SALPINGO-OOPHORITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEBACEOUS GLAND INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPSIS	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SINUSITIS	n/a	1783	100,0	46	2,6	1822	100,0	51	2,8	0,92		Algorithm converged.	0,61	1,38	-0,002		Algorithm converged.	-0,013	0,008	0,92		Algorithm converged.	0,62	1,37	0,6844		1,08		Algorithm converged.	0,73	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUSITIS BACTERIAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN CANDIDA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SKIN INFECTION	n/a	1783	100,0	39	2,2	1822	100,0	30	1,6	1,34		Algorithm converged.	0,83	2,16	0,005		Algorithm converged.	-0,004	0,014	1,33		Algorithm converged.	0,83	2,13	0,2377		0,75		Algorithm converged.	0,47	1,21
	SOFT TISSUE INFECTION	n/a	1783	100,0	6	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STAPHYLOCOCCAL INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	STAPHYLOCOCCAL SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	STAPHYLOCOCCAL SKIN INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STREPTOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STREPTOCOCCAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	STRONGYLOIDIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	SUBCUTANEOUS ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TINEA CAPITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TINEA CRURIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TINEA INFECTION	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	TINEA PEDIS	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONSILLITIS	n/a	1783	100,0	8	0,4	1822	100,0	13	0,7	0,63		Algorithm converged.	0,26	1,52	-0,003		Algorithm converged.	-0,008	0,002		0,63		Algorithm converged.	0,26	1,51	0,3006		1,59		Algorithm converged.	0,66	3,83
	TOOTH ABSCESS	n/a	1783	100,0	12	0,7	1822	100,0	10	0,5	1,23		Algorithm converged.	0,53	2,85	0,001		Algorithm converged.	-0,004	0,006		1,23		Algorithm converged.	0,53	2,83	0,6328		0,82		Algorithm converged.	0,35	1,88
	TOOTH INFECTION	n/a	1783	100,0	13	0,7	1822	100,0	15	0,8	0,88		Algorithm converged.	0,42	1,86	-0,001		Algorithm converged.	-0,007	0,005		0,89		Algorithm converged.	0,42	1,86	0,7476		1,13		Algorithm converged.	0,54	2,37
	TRACHEITIS	n/a	1783	100,0	8	0,4	1822	100,0	10	0,5	0,82		Algorithm converged.	0,32	2,07	-0,001		Algorithm converged.	-0,006	0,004		0,82		Algorithm converged.	0,32	2,07	0,6702		1,22		Algorithm converged.	0,48	3,09
	TRACHEOBRONCHITIS	n/a	1783	100,0	5	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRICHOPHYTOSIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	139	7,8	1822	100,0	136	7,5	1,05		Algorithm converged.	0,82	1,34	0,003		Algorithm converged.	-0,014	0,021		1,04		Algorithm converged.	0,83	1,31	0,7077		0,96		Algorithm converged.	0,76	1,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URETHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY TRACT INFECTION	n/a	1783	100,0	139	7,8	1822	100,0	126	6,9	1,14		Algorithm converged.	0,89	1,46	0,009		Algorithm converged.	-0,008	0,026	1,13		Algorithm converged.	0,89	1,42	0,3115		0,89		Algorithm converged.	0,70	1,12
	URINARY TRACT INFECTION ENTEROCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION PSEUDOMONAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URINARY TRACT INFECTION STAPHYLOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UTERINE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VAGINAL ABSCESS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	n/a	1783	100,0	23	1,3	1822	100,0	27	1,5	0,87		Algorithm converged.	0,50	1,52	-0,002		Algorithm converged.	-0,010	0,006		0,87		Algorithm converged.	0,50	1,51	0,6226		1,15		Algorithm converged.	0,66	2,00
	VAGINITIS GARDNERELLA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VARICELLA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	VARICELLA ZOSTER VIRUS INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	VASCULAR DEVICE INFECTION	n/a	1783	100,0	5	0,3	1822	100,0	11	0,6	0,46		Algorithm converged.	0,16	1,34	-0,003		Algorithm converged.	-0,008	0,001		0,46		Algorithm converged.	0,16	1,33	0,1543			2,15		Algorithm converged.	0,75	6,18	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR NEURONITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VESTIBULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VIRAL INFECTION	n/a	1783	100,0	17	1,0	1822	100,0	14	0,8	1,24		Algorithm converged.	0,61	2,53	0,002		Algorithm converged.	-0,004	0,008	1,24		Algorithm converged.	0,61	2,51	0,5482		0,81		Algorithm converged.	0,40	1,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL PHARYNGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL RASH	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	VIRAL RHINITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL SINUSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL TRACHEITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	VULVAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	8	0,4	0,13		Algorithm converged.	0,02	1,02	-0,004		Algorithm converged.	-0,007	-0,001	0,13		Algorithm converged.	0,02	1,02	0,0522		7,83		Algorithm converged.	0,98	62,53
	VULVOVAGINAL CANDIDIASIS	n/a	1783	100,0	18	1,0	1822	100,0	6	0,3	3,09		Algorithm converged.	1,22	7,79	0,007		Algorithm converged.	0,001	0,012	3,07		Algorithm converged.	1,22	7,70	0,0172		0,33		Algorithm converged.	0,13	0,82
	VULVOVAGINAL MYCOTIC INFECTION	n/a	1783	100,0	24	1,3	1822	100,0	15	0,8	1,64		Algorithm converged.	0,86	3,14	0,005		Algorithm converged.	-0,002	0,012	1,63		Algorithm converged.	0,86	3,11	0,1332		0,61		Algorithm converged.	0,32	1,16
	VULVOVAGINITIS	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	WOUND ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WOUND INFECTION	n/a	1783	100,0	13	0,7	1822	100,0	10	0,5	1,33		Algorithm converged.	0,58	3,04	0,002		Algorithm converged.	-0,003	0,007	1,33		Algorithm converged.	0,58	3,02	0,4982		0,75		Algorithm converged.	0,33	1,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION STAPHYLOCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	474	26,6	1822	100,0	448	24,6	1,11		Algorithm converged.	0,96	1,29	0,020		Algorithm converged.	-0,009	0,048	1,08		Algorithm converged.	0,97	1,21	0,1698		0,92		Algorithm converged.	0,83	1,03
	ACCIDENTAL OVERDOSE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANIMAL BITE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	ANIMAL SCRATCH	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANKLE FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARTHROPOD BITE	n/a	1783	100,0	8	0,4	1822	100,0	7	0,4	1,17		Algorithm converged.	0,42	3,23	0,001		Algorithm converged.	-0,004	0,005	1,17		Algorithm converged.	0,42	3,21	0,7638		0,86		Algorithm converged.	0,31	2,36
	ARTHROPOD STING	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AVULSION FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AXILLARY WEB SYNDROME	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	BITE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	BREAST PROCEDURAL COMPLICATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BURN ORAL CAVITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	BURNS SECOND DEGREE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEMICAL BURN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEMICAL BURNS OF EYE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEMICAL PHLEBITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHILLBLAINS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONCUSSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONTUSION	n/a	1783	100,0	20	1,1	1822	100,0	17	0,9	1,20		Algorithm converged.	0,63	2,31	0,002		Algorithm converged.	-0,005	0,008	1,20		Algorithm converged.	0,63	2,29	0,5747		0,83		Algorithm converged.	0,44	1,58
	DENTAL RESTORATION FAILURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPICONDYLITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ESCHAR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE CONTUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYE INJURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACIAL BONES FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FALL	n/a	1783	100,0	11	0,6	1822	100,0	14	0,8	0,80		Algorithm converged.	0,36	1,77	-0,002		Algorithm converged.	-0,007	0,004	0,80		Algorithm converged.	0,37	1,76	0,5846		1,25		Algorithm converged.	0,57	2,74
	FEMORAL NECK FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FOOT FRACTURE	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005	1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOREIGN BODY IN THROAT	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	FRACTURED SACRUM	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)									
	GASTROINTESTINAL INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE									
	GINGIVAL INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRAFT THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAND FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	HUMERUS FRACTURE	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004		4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	ILIUM FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INCISION SITE COMPLICATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	INCISION SITE ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	INCISION SITE INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	INCISION SITE PAIN	n/a	1783	100,0	11	0,6	1822	100,0	11	0,6	1,02		Algorithm converged.	0,44	2,36	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,44	2,35	0,9594			0,98		Algorithm converged.	0,43	2,25	
	INFUSION RELATED REACTION	n/a	1783	100,0	71	4,0	1822	100,0	65	3,6	1,12		Algorithm converged.	0,80	1,58	0,004		Algorithm converged.	-0,008	0,017		1,12		Algorithm converged.	0,80	1,55	0,5139			0,90		Algorithm converged.	0,64	1,25	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	JOINT INJURY	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	LIGAMENT SPRAIN	n/a	1783	100,0	7	0,4	1822	100,0	9	0,5	0,79		Algorithm converged.	0,30	2,14	-0,001		Algorithm converged.	-0,005	0,003	0,79		Algorithm converged.	0,30	2,13	0,6479		1,26		Algorithm converged.	0,47	3,37
	LIMB INJURY	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,005	0,001	0,34		Algorithm converged.	0,07	1,69	0,1868		2,94		Algorithm converged.	0,59	14,53
	LOWER LIMB FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE RUPTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE STRAIN	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	NAIL INJURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOCONIOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX TRAUMATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POISONING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POST PROCEDURAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POST PROCEDURAL SWELLING	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	POSTMASTECTOMY LYMPHOEDEMA SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL DIZZINESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCEDURAL PAIN	n/a	1783	100,0	10	0,6	1822	100,0	14	0,8	0,73		Algorithm converged.	0,32	1,64	-0,002		Algorithm converged.	-0,007	0,003	0,73		Algorithm converged.	0,33	1,64	0,4455		1,37		Algorithm converged.	0,61	3,08
	PULMONARY RADIATION INJURY	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	RADIATION ASSOCIATED PAIN	n/a	1783	100,0	9	0,5	1822	100,0	5	0,3	1,84		Algorithm converged.	0,62	5,51	0,002		Algorithm converged.	-0,002	0,006	1,84		Algorithm converged.	0,62	5,48	0,2737		0,54		Algorithm converged.	0,18	1,62
	RADIATION INJURY	n/a	1783	100,0	43	2,4	1822	100,0	41	2,3	1,07		Algorithm converged.	0,70	1,66	0,002		Algorithm converged.	-0,008	0,011	1,07		Algorithm converged.	0,70	1,64	0,7481		0,93		Algorithm converged.	0,61	1,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION NECROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIATION NEUROPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION OESOPHAGITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIATION PNEUMONITIS	n/a	1783	100,0	10	0,6	1822	100,0	5	0,3	2,05		Algorithm converged.	0,70	6,01	0,003		Algorithm converged.	-0,001	0,007	2,04		Algorithm converged.	0,70	5,97	0,1911		0,49		Algorithm converged.	0,17	1,43
	RADIATION SKIN INJURY	n/a	1783	100,0	244	13,7	1822	100,0	204	11,2	1,26		Algorithm converged.	1,03	1,53	0,025		Algorithm converged.	0,003	0,046	1,22		Algorithm converged.	1,03	1,45	0,0239		0,82		Algorithm converged.	0,69	0,97
	RADIUS FRACTURE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RIB FRACTURE	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	ROAD TRAFFIC ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCAR	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEROMA	n/a	1783	100,0	10	0,6	1822	100,0	13	0,7	0,78		Algorithm converged.	0,34	1,79	-0,002		Algorithm converged.	-0,007	0,004	0,79		Algorithm converged.	0,35	1,79	0,5659		1,27		Algorithm converged.	0,56	2,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN ABRASION	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	SKIN INJURY	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204429215 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN LACERATION	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	SPINAL COMPRESSION FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRESS FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TENDON INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDON RUPTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THERMAL BURN	n/a	1783	100,0	13	0,7	1822	100,0	11	0,6	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,004	0,007	1,21		Algorithm converged.	0,54	2,69	0,6440		0,83		Algorithm converged.	0,37	1,84
	THORACIC VERTEBRAL FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TIBIA FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	TOOTH FRACTURE	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19	
	TOXICITY TO VARIOUS AGENTS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90	
	TRANSFUSION REACTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.5818616 4 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TRAUMATIC HAEMATOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ULNA FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	UPPER LIMB FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834			1,96		Algorithm converged.	0,18	21,57	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR ACCESS COMPLICATION	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	VENOUS INJURY	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	VIITH NERVE INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL INJURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND	n/a	1783	100,0	7	0,4	1822	100,0	7	0,4	1,02		Algorithm converged.	0,36	2,92	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,36	2,91	0,9676		0,98		Algorithm converged.	0,34	2,78
	WOUND COMPLICATION	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3	1,36		Algorithm converged.	0,47	3,94	0,001		Algorithm converged.	-0,003	0,005	1,36		Algorithm converged.	0,47	3,92	0,5661		0,73		Algorithm converged.	0,26	2,11
	WOUND DEHISCENCE	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	WOUND HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND SECRETION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WRIST FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
INVESTIGATION	-Total	n/a	1783	100,0	755	42,3	1822	100,0	804	44,1	0,93		Algorithm converged.	0,82	1,06	-0,018		Algorithm converged.	-0,050	0,015	0,96		Algorithm converged.	0,89	1,03	0,2802		1,04		Algorithm converged.	0,97	1,12
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	176	9,9	1822	100,0	196	10,8	0,91		Algorithm converged.	0,73	1,13	-0,009		Algorithm converged.	-0,029	0,011	0,92		Algorithm converged.	0,76	1,11	0,3820		1,09		Algorithm converged.	0,90	1,32
	ASPARTATE AMINOTRANSFERASE	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	ASPARTATE AMINOTRANSFERASE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	119	6,7	1822	100,0	130	7,1	0,93		Algorithm converged.	0,72	1,20	-0,005		Algorithm converged.	-0,021	0,012	0,94		Algorithm converged.	0,74	1,19	0,5854		1,07		Algorithm converged.	0,84	1,36
	BILIRUBIN CONJUGATED INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BLOOD ALKALINE PHOSPHATASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BLOOD ALKALINE PHOSPHATASE INCREASED	n/a	1783	100,0	31	1,7	1822	100,0	40	2,2	0,79		Algorithm converged.	0,49	1,27	-0,005		Algorithm converged.	-0,014	0,004	0,79		Algorithm converged.	0,50	1,26	0,3249		1,26		Algorithm converged.	0,79	2,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD BILIRUBIN INCREASED	n/a	1783	100,0	14	0,8	1822	100,0	10	0,5	1,43		Algorithm converged.	0,64	3,24	0,002		Algorithm converged.	-0,003	0,008	1,43		Algorithm converged.	0,64	3,21	0,3855		0,70		Algorithm converged.	0,31	1,57
	BLOOD BILIRUBIN UNCONJUGATED INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CALCIUM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CALCIUM DECREASED	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHLORIDE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD CHOLESTEROL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD CHOLESTEROL INCREASED	n/a	1783	100,0	8	0,4	1822	100,0	12	0,7	0,68		Algorithm converged.	0,28	1,67	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,28	1,66	0,3991		1,47		Algorithm converged.	0,60	3,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATINE PHOSPHOKINASE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CREATININE INCREASED	n/a	1783	100,0	13	0,7	1822	100,0	9	0,5	1,48		Algorithm converged.	0,63	3,47	0,002		Algorithm converged.	-0,003	0,007	1,48		Algorithm converged.	0,63	3,44	0,3678		0,68		Algorithm converged.	0,29	1,58
	BLOOD GLUCOSE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD GLUCOSE FLUCTUATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	BLOOD LACTATE DEHYDROGENASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD LACTATE DEHYDROGENASE DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE INCREASED	n/a	1783	100,0	26	1,5	1822	100,0	18	1,0	1,48		Algorithm converged.	0,81	2,71	0,005		Algorithm converged.	-0,002	0,012		1,48		Algorithm converged.	0,81	2,68	0,2015			0,68		Algorithm converged.	0,37	1,23
	BLOOD MAGNESIUM DECREASED	n/a	1783	100,0	9	0,5	1822	100,0	9	0,5	1,02		Algorithm converged.	0,40	2,58	0,000		Algorithm converged.	-0,004	0,005		1,02		Algorithm converged.	0,41	2,57	0,9633			0,98		Algorithm converged.	0,39	2,46
	BLOOD MAGNESIUM INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63
	BLOOD PHOSPHORUS DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827			0,98		Algorithm converged.	0,14	6,94
	BLOOD PHOSPHORUS INCREASED	n/a	1783	100,0	7	0,4	1822	100,0	4	0,2	1,79		Algorithm converged.	0,52	6,13	0,002		Algorithm converged.	-0,002	0,005		1,79		Algorithm converged.	0,52	6,10	0,3531			0,56		Algorithm converged.	0,16	1,91
	BLOOD POTASSIUM DECREASED	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005		1,53		Algorithm converged.	0,43	5,42	0,5076			0,65		Algorithm converged.	0,18	2,31
	BLOOD POTASSIUM INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63
	BLOOD PRESSURE DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DIASTOLIC DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD PRESSURE DIASTOLIC INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD PRESSURE INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001		0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	BLOOD SODIUM DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD SODIUM INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD TRIGLYCERIDES INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	BLOOD UREA DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD UREA INCREASED	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	BLOOD URIC ACID INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD URINE PRESENT	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	BODY TEMPERATURE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREATH SOUNDS ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	C-REACTIVE PROTEIN INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,005	0,001	0,34		Algorithm converged.	0,07	1,69	0,1868		2,94		Algorithm converged.	0,59	14,53
	CARBOHYDRATE ANTIGEN 125 INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	CARBOHYDRATE ANTIGEN 15-3 INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	CARDIAC MURMUR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
	CLOSTRIDIUM TEST POSITIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE									
	CREATININE RENAL CLEARANCE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DELTARETROVIRUS TEST POSITIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ECHOCARDIOGRAM ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	EJECTION FRACTION DECREASED	n/a	1783	100,0	87	4,9	1822	100,0	112	6,1	0,78		Algorithm converged.	0,59	1,04	-0,013		Algorithm converged.	-0,028	0,002		0,79		Algorithm converged.	0,60	1,04	0,0965			1,26		Algorithm converged.	0,96	1,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ELECTROCARDIOGRAM QT PROLONGED	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ELECTROCARDIOGRAM ST-T CHANGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ELECTROCARDIOGRAM T WAVE ABNORMAL	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM T WAVE INVERSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EOSINOPHIL COUNT DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EOSINOPHIL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FORCED EXPIRATORY VOLUME DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GAMMA-GLUTAMYLTRANSFERASE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	n/a	1783	100,0	18	1,0	1822	100,0	35	1,9	0,52		Algorithm converged.	0,29	0,92	-0,009		Algorithm converged.	-0,017	-0,001	0,53		Algorithm converged.	0,30	0,92	0,0256		1,90		Algorithm converged.	1,08	3,35
	GLOMERULAR FILTRATION RATE DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GLYCOSYLATED HAEMOGLOBIN INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMATOCRIT DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMOGLOBIN	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001		0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	HAEMOGLOBIN DECREASED	n/a	1783	100,0	55	3,1	1822	100,0	59	3,2	0,95		Algorithm converged.	0,65	1,38	-0,002		Algorithm converged.	-0,013	0,010		0,95		Algorithm converged.	0,66	1,37	0,7923		1,05		Algorithm converged.	0,73	1,51

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HAEMOGLOBIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	HAPTOGLOBIN DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	HEART RATE INCREASED	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,21	5,06	0,9788			0,98		Algorithm converged.	0,20	4,84	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HELICOBACTER TEST POSITIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC ENZYME ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC ENZYME INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HUMAN CHORIONIC GONADOTROPIN INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIPASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIVER FUNCTION TEST INCREASED	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004		1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	LYMPHOCYTE COUNT DECREASED	n/a	1783	100,0	15	0,8	1822	100,0	10	0,5	1,54		Algorithm converged.	0,69	3,43	0,003		Algorithm converged.	-0,003	0,008		1,53		Algorithm converged.	0,69	3,40	0,2939		0,65		Algorithm converged.	0,29	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOCYTE COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MEGAKARYOCYTES ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	METAMYELOCYTE COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONONUCLEAR CELL COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUTROPHIL COUNT	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003		0,73		Algorithm converged.	0,23	2,30	0,5902		1,37		Algorithm converged.	0,44	4,31
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	262	14,7	1822	100,0	265	14,5	1,01		Algorithm converged.	0,84	1,22	0,001		Algorithm converged.	-0,022	0,025		1,01		Algorithm converged.	0,86	1,18	0,8987		0,99		Algorithm converged.	0,85	1,16
	NEUTROPHIL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHYSICAL EXAMINATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHYSICAL EXAMINATION ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PLATELET COUNT DECREASED	n/a	1783	100,0	63	3,5	1822	100,0	64	3,5	1,01		Algorithm converged.	0,71	1,43	0,000		Algorithm converged.	-0,012	0,012	1,01		Algorithm converged.	0,71	1,42	0,9731		0,99		Algorithm converged.	0,71	1,40

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT INCREASED	n/a	1783	100,0	10	0,6	1822	100,0	8	0,4	1,28		Algorithm converged.	0,50	3,25	0,001		Algorithm converged.	-0,003	0,006	1,28		Algorithm converged.	0,51	3,23	0,6049		0,78		Algorithm converged.	0,31	1,98
	PROTEIN TOTAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROTEIN TOTAL DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROTEIN URINE PRESENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RED BLOOD CELL COUNT DECREASED	n/a	1783	100,0	16	0,9	1822	100,0	12	0,7	1,37		Algorithm converged.	0,64	2,90	0,002		Algorithm converged.	-0,003	0,008	1,36		Algorithm converged.	0,65	2,87	0,4162		0,73		Algorithm converged.	0,35	1,55
	SERUM FERRITIN DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMEAR CERVIX ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THYROID FUNCTION TEST ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID FUNCTION TEST NORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSAMINASES DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSAMINASES INCREASED	n/a	1783	100,0	17	1,0	1822	100,0	18	1,0	0,96		Algorithm converged.	0,50	1,88	0,000		Algorithm converged.	-0,007	0,006		0,97		Algorithm converged.	0,50	1,87	0,9159		1,04		Algorithm converged.	0,54	2,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSFERRIN SATURATION DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TROPONIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN T INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINE ANALYSIS ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	URINE OUTPUT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITAMIN B12 DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VITAMIN D DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	WEIGHT DECREASED	n/a	1783	100,0	140	7,9	1822	100,0	66	3,6	2,27		Algorithm converged.	1,68	3,06	0,042		Algorithm converged.	0,027	0,057	2,17		Algorithm converged.	1,63	2,88	<.0001		0,46		Algorithm converged.	0,35	0,61
	WEIGHT INCREASED	n/a	1783	100,0	46	2,6	1822	100,0	104	5,7	0,44		Algorithm converged.	0,31	0,62	-0,031		Algorithm converged.	-0,044	-0,018	0,45		Algorithm converged.	0,32	0,64	<.0001		2,21		Algorithm converged.	1,57	3,11
	WHITE BLOOD CELL COUNT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	203	11,4	1822	100,0	169	9,3	1,26		Algorithm converged.	1,01	1,56	0,021		Algorithm converged.	0,001	0,041	1,23		Algorithm converged.	1,01	1,49	0,0378		0,81		Algorithm converged.	0,67	0,99
	WHITE BLOOD CELL COUNT INCREASED	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	633	35,5	1822	100,0	560	30,7	1,24		Algorithm converged.	1,08	1,43	0,048		Algorithm converged.	0,017	0,078	1,16		Algorithm converged.	1,05	1,27	0,0024		0,87		Algorithm converged.	0,79	0,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ACIDOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	APPETITE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CACHEXIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CELL DEATH	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DECREASED APPETITE	n/a	1783	100,0	427	23,9	1822	100,0	373	20,5	1,22		Algorithm converged.	1,05	1,43	0,035		Algorithm converged.	0,008	0,062	1,17		Algorithm converged.	1,03	1,32	0,0122		0,85		Algorithm converged.	0,76	0,97
	DEHYDRATION	n/a	1783	100,0	61	3,4	1822	100,0	39	2,1	1,62		Algorithm converged.	1,08	2,43	0,013		Algorithm converged.	0,002	0,024	1,60		Algorithm converged.	1,08	2,38	0,0204		0,63		Algorithm converged.	0,42	0,93
	DIABETES MELLITUS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETIC METABOLIC DECOMPENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSLIPIDAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	ELECTROLYTE IMBALANCE	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	FAILURE TO THRIVE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FLUID RETENTION	n/a	1783	100,0	17	1,0	1822	100,0	10	0,5	1,74		Algorithm converged.	0,80	3,82	0,004		Algorithm converged.	-0,002	0,010	1,74		Algorithm converged.	0,80	3,78	0,1643		0,58		Algorithm converged.	0,26	1,25
	FOLATE DEFICIENCY	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	FOOD AVERSION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GOUT	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOCHROMATOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERCALCAEMIA	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08
	HYPERCHLORAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	HYPERCHOLESTEROLAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	HYPERGLYCAEMIA	n/a	1783	100,0	27	1,5	1822	100,0	37	2,0	0,74		Algorithm converged.	0,45	1,22	-0,005		Algorithm converged.	-0,014	0,003	0,75		Algorithm converged.	0,46	1,22	0,2422		1,34		Algorithm converged.	0,82	2,19
	HYPERKALAEMIA	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005	2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95
	HYPERMAGNESAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	HYPERNATRAEMIA	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003	0,88		Algorithm converged.	0,29	2,60	0,8114		1,14		Algorithm converged.	0,38	3,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPHOSPHATAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTRIGLYCERIDAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	11	0,6	0,18		Algorithm converged.	0,04	0,84	-0,005		Algorithm converged.	-0,009	-0,001	0,19		Algorithm converged.	0,04	0,84	0,0284		5,38		Algorithm converged.	1,19	24,25
	HYPERURICAEMIA	n/a	1783	100,0	4	0,2	1822	100,0	7	0,4	0,58		Algorithm converged.	0,17	1,99	-0,002		Algorithm converged.	-0,005	0,002	0,58		Algorithm converged.	0,17	1,99	0,3900		1,71		Algorithm converged.	0,50	5,84
	HYPOALBUMINAEMIA	n/a	1783	100,0	6	0,3	1822	100,0	5	0,3	1,23		Algorithm converged.	0,37	4,03	0,001		Algorithm converged.	-0,003	0,004	1,23		Algorithm converged.	0,37	4,01	0,7359		0,82		Algorithm converged.	0,25	2,67
	HYPOCALCAEMIA	n/a	1783	100,0	34	1,9	1822	100,0	22	1,2	1,59		Algorithm converged.	0,93	2,73	0,007		Algorithm converged.	-0,001	0,015	1,58		Algorithm converged.	0,93	2,69	0,0925		0,63		Algorithm converged.	0,37	1,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCHLORAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOGLYCAEMIA	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	HYPOKALAEMIA	n/a	1783	100,0	108	6,1	1822	100,0	81	4,4	1,39		Algorithm converged.	1,03	1,86	0,016		Algorithm converged.	0,002	0,031	1,36		Algorithm converged.	1,03	1,80	0,0307		0,73		Algorithm converged.	0,55	0,97
	HYPOMAGNESAEMIA	n/a	1783	100,0	107	6,0	1822	100,0	60	3,3	1,87		Algorithm converged.	1,36	2,59	0,027		Algorithm converged.	0,013	0,041	1,82		Algorithm converged.	1,34	2,48	0,0001		0,55		Algorithm converged.	0,40	0,75
	HYPONATRAEMIA	n/a	1783	100,0	14	0,8	1822	100,0	18	1,0	0,79		Algorithm converged.	0,39	1,60	-0,002		Algorithm converged.	-0,008	0,004	0,79		Algorithm converged.	0,40	1,59	0,5174		1,26		Algorithm converged.	0,63	2,52
	HYPOPHAGIA	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	14	0,8	1822	100,0	11	0,6	1,30		Algorithm converged.	0,59	2,88	0,002		Algorithm converged.	-0,004	0,007	1,30		Algorithm converged.	0,59	2,86	0,5128		0,77		Algorithm converged.	0,35	1,69
	HYPOPROTEINAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOVOLAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	INCREASED APPETITE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	IRON DEFICIENCY	n/a	1783	100,0	7	0,4	1822	100,0	2	0,1	3,59		Algorithm converged.	0,74	17,29	0,003		Algorithm converged.	0,000	0,006	3,58		Algorithm converged.	0,74	17,19	0,1116		0,28		Algorithm converged.	0,06	1,34
	LACTOSE INTOLERANCE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MAGNESIUM DEFICIENCY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	OBESITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	POLYDIPSIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	TETANY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR LYSIS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TYPE 2 DIABETES MELLITUS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	VITAMIN B12 DEFICIENCY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VITAMIN C DEFICIENCY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITAMIN D DEFICIENCY	n/a	1783	100,0	12	0,7	1822	100,0	12	0,7	1,02		Algorithm converged.	0,46	2,28	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,46	2,27	0,9576		0,98		Algorithm converged.	0,44	2,17
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	1116	62,6	1822	100,0	1185	65,0	0,90		Algorithm converged.	0,79	1,03	-0,024		Algorithm converged.	-0,056	0,007	0,96		Algorithm converged.	0,92	1,01	0,1266		1,04		Algorithm converged.	0,99	1,09
	ARTHRALGIA	n/a	1783	100,0	534	29,9	1822	100,0	583	32,0	0,91		Algorithm converged.	0,79	1,05	-0,020		Algorithm converged.	-0,051	0,010	0,94		Algorithm converged.	0,85	1,03	0,1839		1,07		Algorithm converged.	0,97	1,18
	ARTHRITIS	n/a	1783	100,0	13	0,7	1822	100,0	12	0,7	1,11		Algorithm converged.	0,50	2,43	0,001		Algorithm converged.	-0,005	0,006	1,11		Algorithm converged.	0,51	2,42	0,7988		0,90		Algorithm converged.	0,41	1,97
	ARTHROPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY MASS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACK PAIN	n/a	1783	100,0	156	8,7	1822	100,0	183	10,0	0,86		Algorithm converged.	0,69	1,07	-0,013		Algorithm converged.	-0,032	0,006	0,87		Algorithm converged.	0,71	1,07	0,1835		1,15		Algorithm converged.	0,94	1,41
	BONE FORMATION INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BONE PAIN	n/a	1783	100,0	173	9,7	1822	100,0	192	10,5	0,91		Algorithm converged.	0,73	1,13	-0,008		Algorithm converged.	-0,028	0,011	0,92		Algorithm converged.	0,76	1,12	0,4061		1,09		Algorithm converged.	0,89	1,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BURSITIS	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002		0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	CHEST WALL MASS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COCCYDYNIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONNECTIVE TISSUE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COSTOCHONDRITIS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	DACTYLITIS	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	DUPUYTREN'S CONTRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	EXOSTOSIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	FIBROMYALGIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	FLANK PAIN	n/a	1783	100,0	6	0,3	1822	100,0	10	0,5	0,61		Algorithm converged.	0,22	1,69	-0,002		Algorithm converged.	-0,006	0,002		0,61		Algorithm converged.	0,22	1,68	0,3425			1,63		Algorithm converged.	0,59	4,48	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GROIN PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	HAEMARTHROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERVERTEBRAL DISC PROTRUSION	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	JAW CLICKING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001		0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	JOINT INSTABILITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT LOCK	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT NOISE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	JOINT RANGE OF MOTION DECREASED	n/a	1783	100,0	10	0,6	1822	100,0	12	0,7	0,85		Algorithm converged.	0,37	1,97	-0,001		Algorithm converged.	-0,006	0,004	0,85		Algorithm converged.	0,37	1,97	0,7066		1,17		Algorithm converged.	0,51	2,71
	JOINT STIFFNESS	n/a	1783	100,0	13	0,7	1822	100,0	11	0,6	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,004	0,007	1,21		Algorithm converged.	0,54	2,69	0,6440		0,83		Algorithm converged.	0,37	1,84
	JOINT SWELLING	n/a	1783	100,0	11	0,6	1822	100,0	10	0,5	1,12		Algorithm converged.	0,48	2,66	0,001		Algorithm converged.	-0,004	0,006	1,12		Algorithm converged.	0,48	2,64	0,7884		0,89		Algorithm converged.	0,38	2,09
	LIMB DISCOMFORT	n/a	1783	100,0	13	0,7	1822	100,0	16	0,9	0,83		Algorithm converged.	0,40	1,73	-0,001		Algorithm converged.	-0,007	0,004	0,83		Algorithm converged.	0,40	1,72	0,6170		1,20		Algorithm converged.	0,58	2,50
	LIMB MASS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	MUSCLE ATROPHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE CONTRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE DISCOMFORT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MUSCLE OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE RIGIDITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE SPASMS	n/a	1783	100,0	159	8,9	1822	100,0	85	4,7	2,00		Algorithm converged.	1,52	2,63	0,043		Algorithm converged.	0,026	0,059	1,91		Algorithm converged.	1,48	2,47	<.0001		0,52		Algorithm converged.	0,41	0,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE TIGHTNESS	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002		0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	MUSCLE TWITCHING	n/a	1783	100,0	11	0,6	1822	100,0	7	0,4	1,61		Algorithm converged.	0,62	4,16	0,002		Algorithm converged.	-0,002	0,007		1,61		Algorithm converged.	0,62	4,13	0,3261		0,62		Algorithm converged.	0,24	1,60
	MUSCULAR WEAKNESS	n/a	1783	100,0	25	1,4	1822	100,0	32	1,8	0,80		Algorithm converged.	0,47	1,35	-0,004		Algorithm converged.	-0,012	0,005		0,80		Algorithm converged.	0,48	1,34	0,3951		1,25		Algorithm converged.	0,75	2,10
	MUSCULOSKELETAL CHEST PAIN	n/a	1783	100,0	51	2,9	1822	100,0	55	3,0	0,95		Algorithm converged.	0,64	1,39	-0,002		Algorithm converged.	-0,013	0,009		0,95		Algorithm converged.	0,65	1,38	0,7785		1,06		Algorithm converged.	0,73	1,54
	MUSCULOSKELETAL DISCOMFORT	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005		1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31
	MUSCULOSKELETAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULOSKELETAL PAIN	n/a	1783	100,0	103	5,8	1822	100,0	125	6,9	0,83		Algorithm converged.	0,64	1,09	-0,011		Algorithm converged.	-0,027	0,005		0,84		Algorithm converged.	0,65	1,08	0,1820		1,19		Algorithm converged.	0,92	1,53
	MUSCULOSKELETAL STIFFNESS	n/a	1783	100,0	19	1,1	1822	100,0	33	1,8	0,58		Algorithm converged.	0,33	1,03	-0,007		Algorithm converged.	-0,015	0,000		0,59		Algorithm converged.	0,34	1,03	0,0637		1,70		Algorithm converged.	0,97	2,98

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		
	MYALGIA	n/a	1783	100,0	461	25,9	1822	100,0	528	29,0	0,85		Algorithm converged.	0,74	0,99	-0,031		Algorithm converged.	-0,060	-0,002		0,89		Algorithm converged.	0,80	0,99	0,0358		1,12		Algorithm converged.	1,01	1,25		
	MYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE		
	MYOSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63		
	NECK PAIN	n/a	1783	100,0	32	1,8	1822	100,0	34	1,9	0,96		Algorithm converged.	0,59	1,56	-0,001		Algorithm converged.	-0,009	0,008		0,96		Algorithm converged.	0,60	1,55	0,8731		1,04		Algorithm converged.	0,64	1,68		
	OSTEOARTHRITIS	n/a	1783	100,0	10	0,6	1822	100,0	12	0,7	0,85		Algorithm converged.	0,37	1,97	-0,001		Algorithm converged.	-0,006	0,004		0,85		Algorithm converged.	0,37	1,97	0,7066		1,17		Algorithm converged.	0,51	2,71		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OSTEONECROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OSTEOPENIA	n/a	1783	100,0	22	1,2	1822	100,0	13	0,7	1,74		Algorithm converged.	0,87	3,46	0,005		Algorithm converged.	-0,001	0,012	1,73		Algorithm converged.	0,87	3,42	0,1157		0,58		Algorithm converged.	0,29	1,14
	OSTEOPOROSIS	n/a	1783	100,0	27	1,5	1822	100,0	24	1,3	1,15		Algorithm converged.	0,66	2,00	0,002		Algorithm converged.	-0,006	0,010	1,15		Algorithm converged.	0,67	1,98	0,6167		0,87		Algorithm converged.	0,50	1,50
	PAIN IN EXTREMITY	n/a	1783	100,0	181	10,2	1822	100,0	202	11,1	0,91		Algorithm converged.	0,73	1,12	-0,009		Algorithm converged.	-0,029	0,011	0,92		Algorithm converged.	0,76	1,11	0,3625		1,09		Algorithm converged.	0,90	1,32
	PAIN IN JAW	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12
	PERIARTHRITIS	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIOSTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLANTAR FASCIITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYARTHRITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PSORIATIC ARTHROPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	RHEUMATIC DISORDER	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77	
	RHEUMATOID ARTHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ROTATOR CUFF SYNDROME	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005	1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	SACRAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	SACROILIITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	SJOGREN'S SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	SPINAL OSTEOARTHRITIS	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004		1,28		Algorithm converged.	0,34	4,75	0,7149			0,78		Algorithm converged.	0,21	2,91	
	SPINAL PAIN	n/a	1783	100,0	11	0,6	1822	100,0	9	0,5	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,006		1,25		Algorithm converged.	0,52	3,01	0,6199			0,80		Algorithm converged.	0,33	1,93	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL STENOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SYNOVIAL CYST	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	SYSTEMIC LUPUS ERYTHEMATOSUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	TEMPOROMANDIBULAR JOINT SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	TENDINOUS CONTRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDON DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TENDON PAIN	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	TENDONITIS	n/a	1783	100,0	9	0,5	1822	100,0	7	0,4	1,32		Algorithm converged.	0,49	3,54	0,001		Algorithm converged.	-0,003	0,006		1,31		Algorithm converged.	0,49	3,52	0,5873		0,76		Algorithm converged.	0,28	2,04
	TENOSYNOVITIS	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005		5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENOSYNOVITIS STENOSANS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TORTICOLLIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRIGGER FINGER	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	TRISMUS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	WINGED SCAPULA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	22	1,2	1822	100,0	37	2,0	0,60		Algorithm converged.	0,35	1,03	-0,008		Algorithm converged.	-0,016	0,000	0,61		Algorithm converged.	0,36	1,03	0,0622		1,65		Algorithm converged.	0,97	2,78	
	ACROCHORDON	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ADENOCARCINOMA PANCREAS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANOGENITAL WARTS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BASAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BENIGN BREAST NEOPLASM	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	BENIGN NEOPLASM OF LACRIMAL DUCT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST CANCER IN SITU	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CANCER FATIGUE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID TUMOUR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FIBROADENOMA OF BREAST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk									Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	FIBROMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	GASTRIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMANGIOMA OF LIVER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERGAMMAGLOBULINAEMIA BENIGN MONOCLONAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIPOMA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	LOBULAR BREAST CARCINOMA IN SITU	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHANGIOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MALIGNANT MELANOMA IN SITU	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MELANOCYTIC NAEVUS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	MONOCLONAL GAMMOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYELODYSPLASTIC SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAEVUS HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURILEMMOMA BENIGN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL FIBROMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OVARIAN GERM CELL TERATOMA BENIGN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAPILLARY THYROID CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARATHYROID TUMOUR BENIGN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYOGENIC GRANULOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEBORRHOEIC KERATOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN PAPILLOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL CELL LUNG CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SQUAMOUS CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UTERINE LEIOMYOMA	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	1255	70,4	1822	100,0	1221	67,0	1,17		Algorithm converged.	1,02	1,35	0,034		Algorithm converged.	0,003	0,064	1,05		Algorithm converged.	1,01	1,10	0,0291		0,95		Algorithm converged.	0,91	1,00
	AGEUSIA	n/a	1783	100,0	14	0,8	1822	100,0	12	0,7	1,19		Algorithm converged.	0,55	2,59	0,001		Algorithm converged.	-0,004	0,007	1,19		Algorithm converged.	0,55	2,57	0,6538		0,84		Algorithm converged.	0,39	1,81
	AKATHISIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ALLODYNIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	AMNESIA	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08
	ANOSMIA	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHASIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATAXIA	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	AUDITORY NERVE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.37850919 4 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BALANCE DISORDER	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003		0,85		Algorithm converged.	0,26	2,79	0,7904			1,17		Algorithm converged.	0,36	3,84
	BELL'S PALSY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BRACHIAL PLEXOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BURNING SENSATION	n/a	1783	100,0	10	0,6	1822	100,0	4	0,2	2,56		Algorithm converged.	0,80	8,19	0,003		Algorithm converged.	-0,001	0,007	2,55		Algorithm converged.	0,80	8,13	0,1123		0,39		Algorithm converged.	0,12	1,25	
	CAROTID ARTERY STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	CARPAL TUNNEL SYNDROME	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67	
	CEREBELLAR SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CEREBRAL ISCHAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CERVICAL RADICULOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CERVICOBRACHIAL SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CLONUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	COGNITIVE DISORDER	n/a	1783	100,0	15	0,8	1822	100,0	15	0,8	1,02		Algorithm converged.	0,50	2,10	0,000		Algorithm converged.	-0,006	0,006		1,02		Algorithm converged.	0,50	2,08	0,9526			0,98		Algorithm converged.	0,48	2,00	
	COMPLEX REGIONAL PAIN SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COORDINATION ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEMENTIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEPRESSED LEVEL OF CONSCIOUSNESS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DISTURBANCE IN ATTENTION	n/a	1783	100,0	21	1,2	1822	100,0	15	0,8	1,44		Algorithm converged.	0,74	2,79	0,004		Algorithm converged.	-0,003	0,010		1,43		Algorithm converged.	0,74	2,77	0,2871		0,70		Algorithm converged.	0,36	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	n/a	1783	100,0	215	12,1	1822	100,0	210	11,5	1,05		Algorithm converged.	0,86	1,29	0,005		Algorithm converged.	-0,016	0,026		1,05		Algorithm converged.	0,88	1,25	0,6201		0,96		Algorithm converged.	0,80	1,14
	DIZZINESS POSTURAL	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	DYSAESTHESIA	n/a	1783	100,0	23	1,3	1822	100,0	18	1,0	1,31		Algorithm converged.	0,70	2,44	0,003		Algorithm converged.	-0,004	0,010		1,31		Algorithm converged.	0,71	2,41	0,3940		0,77		Algorithm converged.	0,41	1,41
	DYSARTHRIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	n/a	1783	100,0	306	17,2	1822	100,0	257	14,1	1,26		Algorithm converged.	1,05	1,51	0,031		Algorithm converged.	0,007	0,054		1,22		Algorithm converged.	1,04	1,42	0,0117		0,82		Algorithm converged.	0,71	0,96

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSKINESIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTRIC SHOCK SENSATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESSENTIAL TREMOR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FACIAL NERVE DISORDER	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE CONVULSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FORMICATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	HAEMORRHAGE INTRACRANIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HEAD DISCOMFORT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	HEAD TITUBATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	HEADACHE	n/a	1783	100,0	398	22,3	1822	100,0	424	23,3	0,95		Algorithm converged.	0,81	1,11	-0,009		Algorithm converged.	-0,037	0,018	0,96		Algorithm converged.	0,85	1,08	0,4971		1,04		Algorithm converged.	0,92	1,18	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEMIANOPIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERAESTHESIA	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12
	HYPERGEUSIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPATHIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERSOMNIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	HYPERTONIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	HYPOAESTHESIA	n/a	1783	100,0	65	3,6	1822	100,0	63	3,5	1,06		Algorithm converged.	0,74	1,50	0,002		Algorithm converged.	-0,010	0,014		1,05		Algorithm converged.	0,75	1,48	0,7607		0,95		Algorithm converged.	0,67	1,33
	HYPOGEUSIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOSMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOTONIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	INTERCOSTAL NEURALGIA	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LACUNAR INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LETHARGY	n/a	1783	100,0	21	1,2	1822	100,0	27	1,5	0,79		Algorithm converged.	0,45	1,41	-0,003		Algorithm converged.	-0,011	0,004	0,79		Algorithm converged.	0,45	1,40	0,4268		1,26		Algorithm converged.	0,71	2,22
	LOSS OF CONSCIOUSNESS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	MEMORY IMPAIRMENT	n/a	1783	100,0	29	1,6	1822	100,0	23	1,3	1,29		Algorithm converged.	0,75	2,24	0,004		Algorithm converged.	-0,004	0,011	1,29		Algorithm converged.	0,75	2,22	0,3606		0,78		Algorithm converged.	0,45	1,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENTAL IMPAIRMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MIGRAINE	n/a	1783	100,0	15	0,8	1822	100,0	7	0,4	2,20		Algorithm converged.	0,89	5,41	0,005		Algorithm converged.	-0,001	0,010	2,19		Algorithm converged.	0,89	5,36	0,0860		0,46		Algorithm converged.	0,19	1,12
	MIGRAINE WITH AURA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
	MORTON'S NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE									
	MUSCLE CONTRACTIONS INVOLUNTARY	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39									
	MUSCLE SPASTICITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE									
	NERVE COMPRESSION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)						
	NEURALGIA	n/a	1783	100,0	20	1,1	1822	100,0	20	1,1	1,02		Algorithm converged.	0,55	1,91	0,000		Algorithm converged.	-0,007	0,007		1,02		Algorithm converged.	0,55	1,89	0,9451		0,98		Algorithm converged.	0,53	1,81
	NEURITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUROPATHY PERIPHERAL	n/a	1783	100,0	284	15,9	1822	100,0	268	14,7	1,10		Algorithm converged.	0,92	1,32	0,012		Algorithm converged.	-0,011	0,036		1,08		Algorithm converged.	0,93	1,26	0,3097		0,92		Algorithm converged.	0,79	1,08
	NEUROTOXICITY	n/a	1783	100,0	39	2,2	1822	100,0	40	2,2	1,00		Algorithm converged.	0,64	1,56	0,000		Algorithm converged.	-0,010	0,009		1,00		Algorithm converged.	0,64	1,54	0,9868		1,00		Algorithm converged.	0,65	1,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	OCCIPITAL NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	OPHTHALMIC MIGRAINE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOSTATIC INTOLERANCE	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARAESTHESIA	n/a	1783	100,0	200	11,2	1822	100,0	188	10,3	1,10		Algorithm converged.	0,89	1,36	0,009		Algorithm converged.	-0,011	0,029		1,09		Algorithm converged.	0,90	1,31	0,3842		0,92		Algorithm converged.	0,76	1,11
	PAROSMIA	n/a	1783	100,0	13	0,7	1822	100,0	7	0,4	1,90		Algorithm converged.	0,76	4,78	0,003		Algorithm converged.	-0,001	0,008		1,90		Algorithm converged.	0,76	4,75	0,1707		0,53		Algorithm converged.	0,21	1,32
	PERIPHERAL MOTOR NEUROPATHY	n/a	1783	100,0	13	0,7	1822	100,0	13	0,7	1,02		Algorithm converged.	0,47	2,21	0,000		Algorithm converged.	-0,005	0,006		1,02		Algorithm converged.	0,48	2,20	0,9558		0,98		Algorithm converged.	0,45	2,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL PARALYSIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIPHERAL SENSORY NEUROPATHY	n/a	1783	100,0	320	17,9	1822	100,0	322	17,7	1,02		Algorithm converged.	0,86	1,21	0,003		Algorithm converged.	-0,022	0,028	1,02		Algorithm converged.	0,88	1,17	0,8295		0,98		Algorithm converged.	0,86	1,13
	PHANTOM LIMB SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYNEUROPATHY	n/a	1783	100,0	41	2,3	1822	100,0	40	2,2	1,05		Algorithm converged.	0,67	1,63	0,001		Algorithm converged.	-0,009	0,011	1,05		Algorithm converged.	0,68	1,61	0,8330		0,95		Algorithm converged.	0,62	1,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PRESYNCOPE	n/a	1783	100,0	13	0,7	1822	100,0	15	0,8	0,88		Algorithm converged.	0,42	1,86	-0,001		Algorithm converged.	-0,007	0,005		0,89		Algorithm converged.	0,42	1,86	0,7476		1,13		Algorithm converged.	0,54	2,37
	PSYCHOGENIC SEIZURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOMOTOR HYPERACTIVITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYRAMIDAL TRACT SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESTLESS LEGS SYNDROME	n/a	1783	100,0	11	0,6	1822	100,0	7	0,4	1,61		Algorithm converged.	0,62	4,16	0,002		Algorithm converged.	-0,002	0,007	1,61		Algorithm converged.	0,62	4,13	0,3261		0,62		Algorithm converged.	0,24	1,60
	SCIATICA	n/a	1783	100,0	11	0,6	1822	100,0	14	0,8	0,80		Algorithm converged.	0,36	1,77	-0,002		Algorithm converged.	-0,007	0,004	0,80		Algorithm converged.	0,37	1,76	0,5846		1,25		Algorithm converged.	0,57	2,74
	SEIZURE	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	SENSORY DISTURBANCE	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SENSORY LOSS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SOMNOLENCE	n/a	1783	100,0	16	0,9	1822	100,0	10	0,5	1,64		Algorithm converged.	0,74	3,63	0,003		Algorithm converged.	-0,002	0,009	1,63		Algorithm converged.	0,74	3,59	0,2210		0,61		Algorithm converged.	0,28	1,34
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	n/a	1783	100,0	31	1,7	1822	100,0	21	1,2	1,52		Algorithm converged.	0,87	2,65	0,006		Algorithm converged.	-0,002	0,014	1,51		Algorithm converged.	0,87	2,61	0,1430		0,66		Algorithm converged.	0,38	1,15
	TASTE DISORDER	n/a	1783	100,0	149	8,4	1822	100,0	124	6,8	1,25		Algorithm converged.	0,97	1,60	0,016		Algorithm converged.	-0,002	0,033	1,23		Algorithm converged.	0,98	1,54	0,0791		0,81		Algorithm converged.	0,65	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENSION HEADACHE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THALAMIC INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXIC NEUROPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSIENT ISCHAEMIC ATTACK	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TREMOR	n/a	1783	100,0	11	0,6	1822	100,0	9	0,5	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,006		1,25		Algorithm converged.	0,52	3,01	0,6199		0,80		Algorithm converged.	0,33	1,93
	TRIGEMINAL NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR ENCEPHALOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VOCAL CORD PARESIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PRODUCT ISSUE	-Total	n/a	1783	100,0	8	0,4	1822	100,0	7	0,4	1,17		Algorithm converged.	0,42	3,23	0,001		Algorithm converged.	-0,004	0,005	1,17		Algorithm converged.	0,42	3,21	0,7638		0,86		Algorithm converged.	0,31	2,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE BREAKAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE CONNECTION ISSUE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE DEFECTIVE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE DISLOCATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE ISSUE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE MALFUNCTION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	DEVICE OCCLUSION	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS IN DEVICE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	479	26,9	1822	100,0	457	25,1	1,10		Algorithm converged.	0,95	1,27	0,018		Algorithm converged.	-0,011	0,046		1,07		Algorithm converged.	0,96	1,20	0,2224		0,93		Algorithm converged.	0,84	1,04
	ADJUSTMENT DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADJUSTMENT DISORDER WITH DEPRESSED MOOD	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AFFECT LABILITY	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AFFECTIVE DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	AGITATION	n/a	1783	100,0	6	0,3	1822	100,0	5	0,3	1,23		Algorithm converged.	0,37	4,03	0,001		Algorithm converged.	-0,003	0,004	1,23		Algorithm converged.	0,37	4,01	0,7359		0,82		Algorithm converged.	0,25	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AGORAPHOBIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANXIETY	n/a	1783	100,0	109	6,1	1822	100,0	77	4,2	1,48		Algorithm converged.	1,09	1,99	0,019		Algorithm converged.	0,004	0,033	1,45		Algorithm converged.	1,09	1,92	0,0109		0,69		Algorithm converged.	0,52	0,92
	ANXIETY DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APATHY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CONFUSIONAL STATE	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	DELUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEPRESSED MOOD	n/a	1783	100,0	15	0,8	1822	100,0	11	0,6	1,40		Algorithm converged.	0,64	3,05	0,002		Algorithm converged.	-0,003	0,008	1,39		Algorithm converged.	0,64	3,03	0,4016		0,72		Algorithm converged.	0,33	1,56
	DEPRESSION	n/a	1783	100,0	82	4,6	1822	100,0	78	4,3	1,08		Algorithm converged.	0,78	1,48	0,003		Algorithm converged.	-0,010	0,017	1,07		Algorithm converged.	0,79	1,45	0,6431		0,93		Algorithm converged.	0,69	1,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSIVE SYMPTOM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DISORIENTATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	EMOTIONAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	EMOTIONAL DISTRESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ENURESIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	GENITO-PELVIC PAIN/PENETRATION DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	HALLUCINATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57	
	ILLUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	INSOMNIA	n/a	1783	100,0	285	16,0	1822	100,0	301	16,5	0,96		Algorithm converged.	0,81	1,15	-0,005		Algorithm converged.	-0,029	0,019	0,97		Algorithm converged.	0,83	1,12	0,6628		1,03		Algorithm converged.	0,89	1,20	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRRITABILITY	n/a	1783	100,0	8	0,4	1822	100,0	11	0,6	0,74		Algorithm converged.	0,30	1,85	-0,002		Algorithm converged.	-0,006	0,003		0,74		Algorithm converged.	0,30	1,84	0,5219		1,35		Algorithm converged.	0,54	3,34
	LIBIDO DECREASED	n/a	1783	100,0	11	0,6	1822	100,0	9	0,5	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,006		1,25		Algorithm converged.	0,52	3,01	0,6199		0,80		Algorithm converged.	0,33	1,93
	LIBIDO DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	LOSS OF LIBIDO	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MAJOR DEPRESSION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MANIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENTAL DISORDER	n/a	1783	100,0	6	0,3	1822	100,0	2	0,1	3,07		Algorithm converged.	0,62	15,24	0,002		Algorithm converged.	-0,001	0,005	3,07		Algorithm converged.	0,62	15,17	0,1697		0,33		Algorithm converged.	0,07	1,61
	MENTAL STATUS CHANGES	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIXED ANXIETY AND DEPRESSIVE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MOOD ALTERED	n/a	1783	100,0	18	1,0	1822	100,0	13	0,7	1,42		Algorithm converged.	0,69	2,90	0,003		Algorithm converged.	-0,003	0,009	1,41		Algorithm converged.	0,70	2,88	0,3383		0,71		Algorithm converged.	0,35	1,44
	MOOD SWINGS	n/a	1783	100,0	11	0,6	1822	100,0	11	0,6	1,02		Algorithm converged.	0,44	2,36	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,44	2,35	0,9594		0,98		Algorithm converged.	0,43	2,25
	NERVOUSNESS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NIGHTMARE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ONYCHOPHAGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ORGANIC BRAIN SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PANIC ATTACK	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARASOMNIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERSISTENT DEPRESSIVE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PERSONALITY CHANGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POOR QUALITY SLEEP	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHIATRIC SYMPTOM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	REACTIVE PSYCHOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RESTLESSNESS	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	SELF ESTEEM DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SLEEP DISORDER	n/a	1783	100,0	22	1,2	1822	100,0	18	1,0	1,25		Algorithm converged.	0,67	2,34	0,002		Algorithm converged.	-0,004	0,009	1,25		Algorithm converged.	0,67	2,32	0,4818		0,80		Algorithm converged.	0,43	1,49
	STRESS	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	SUICIDAL IDEATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SUICIDE ATTEMPT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TEARFULNESS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THINKING ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VOMITING PSYCHOGENIC	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	138	7,7	1822	100,0	143	7,8	0,98		Algorithm converged.	0,77	1,26	-0,001		Algorithm converged.	-0,019	0,016	0,99		Algorithm converged.	0,79	1,23	0,9031		1,01		Algorithm converged.	0,81	1,27
	ACUTE KIDNEY INJURY	n/a	1783	100,0	10	0,6	1822	100,0	5	0,3	2,05		Algorithm converged.	0,70	6,01	0,003		Algorithm converged.	-0,001	0,007	2,04		Algorithm converged.	0,70	5,97	0,1911		0,49		Algorithm converged.	0,17	1,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLADDER DISCOMFORT	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLADDER PROLAPSE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	COSTOVERTEBRAL ANGLE TENDERNESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CYSTITIS HAEMORRHAGIC	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYSTITIS INTERSTITIAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CYSTITIS NONINFECTIVE	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3	1,36		Algorithm converged.	0,47	3,94	0,001		Algorithm converged.	-0,003	0,005	1,36		Algorithm converged.	0,47	3,92	0,5661		0,73		Algorithm converged.	0,26	2,11
	DYSURIA	n/a	1783	100,0	53	3,0	1822	100,0	55	3,0	0,98		Algorithm converged.	0,67	1,44	0,000		Algorithm converged.	-0,012	0,011	0,98		Algorithm converged.	0,68	1,43	0,9352		1,02		Algorithm converged.	0,70	1,47
	HAEMATURIA	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTONIC BLADDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCONTINENCE	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	LEUKOCYTURIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICTURITION DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MICTURITION URGENCY	n/a	1783	100,0	9	0,5	1822	100,0	5	0,3	1,84		Algorithm converged.	0,62	5,51	0,002		Algorithm converged.	-0,002	0,006	1,84		Algorithm converged.	0,62	5,48	0,2737		0,54		Algorithm converged.	0,18	1,62
	NEPHROLITHIASIS	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	NOCTURIA	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	POLLAKIURIA	n/a	1783	100,0	21	1,2	1822	100,0	25	1,4	0,86		Algorithm converged.	0,48	1,54	-0,002		Algorithm converged.	-0,009	0,005	0,86		Algorithm converged.	0,48	1,53	0,6036		1,16		Algorithm converged.	0,65	2,07
	POLYURIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROTEINURIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL COLIC	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	RENAL CYST	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	RENAL FAILURE	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	RENAL IMPAIRMENT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	RENAL PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRANGURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STRESS URINARY INCONTINENCE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	URETERIC OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URETEROLITHIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URGE INCONTINENCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY HESITATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY INCONTINENCE	n/a	1783	100,0	6	0,3	1822	100,0	10	0,5	0,61		Algorithm converged.	0,22	1,69	-0,002		Algorithm converged.	-0,006	0,002	0,61		Algorithm converged.	0,22	1,68	0,3425		1,63		Algorithm converged.	0,59	4,48
	URINARY RETENTION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	URINARY TRACT DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	URINARY TRACT INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	URINARY TRACT OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	URINARY TRACT PAIN	n/a	1783	100,0	11	0,6	1822	100,0	3	0,2	3,76		Algorithm converged.	1,05	13,51	0,005		Algorithm converged.	0,000	0,009		3,75		Algorithm converged.	1,05	13,41	0,0423			0,27		Algorithm converged.	0,07	0,96	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINE ODOUR ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UROGENITAL DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	n/a	1783	100,0	322	18,1	1822	100,0	312	17,1	1,07		Algorithm converged.	0,90	1,27	0,009		Algorithm converged.	-0,016	0,034	1,05		Algorithm converged.	0,92	1,21	0,4608		0,95		Algorithm converged.	0,82	1,09
	AMENORRHOEA	n/a	1783	100,0	31	1,7	1822	100,0	30	1,6	1,06		Algorithm converged.	0,64	1,75	0,001		Algorithm converged.	-0,008	0,009	1,06		Algorithm converged.	0,64	1,74	0,8303		0,95		Algorithm converged.	0,58	1,56

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATROPHIC VULVOVAGINITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BARTHOLIN'S CYST	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	BREAST ATROPHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST CALCIFICATIONS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST CYST	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	BREAST DISCHARGE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	BREAST DISCOLOURATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST DISCOMFORT	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	BREAST DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST ENGORGEMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST ENLARGEMENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST HAEMATOMA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	BREAST HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST INDURATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST INFLAMMATION	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	BREAST MASS	n/a	1783	100,0	10	0,6	1822	100,0	2	0,1	5,13		Algorithm converged.	1,12	23,46	0,005		Algorithm converged.	0,001	0,008	5,11		Algorithm converged.	1,12	23,29	0,0351		0,20		Algorithm converged.	0,04	0,89
	BREAST OEDEMA	n/a	1783	100,0	21	1,2	1822	100,0	16	0,9	1,35		Algorithm converged.	0,70	2,59	0,003		Algorithm converged.	-0,004	0,010	1,34		Algorithm converged.	0,70	2,56	0,3739		0,75		Algorithm converged.	0,39	1,42
	BREAST PAIN	n/a	1783	100,0	76	4,3	1822	100,0	80	4,4	0,97		Algorithm converged.	0,70	1,34	-0,001		Algorithm converged.	-0,015	0,012	0,97		Algorithm converged.	0,71	1,32	0,8499		1,03		Algorithm converged.	0,76	1,40
	BREAST SWELLING	n/a	1783	100,0	5	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST TENDERNESS	n/a	1783	100,0	2	0,1	1822	100,0	8	0,4	0,25		Algorithm converged.	0,05	1,20	-0,003		Algorithm converged.	-0,007	0,000	0,26		Algorithm converged.	0,05	1,20	0,0840		3,91		Algorithm converged.	0,83	18,41
	CERVICAL POLYP	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DYSMENORRHOEA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPAREUNIA	n/a	1783	100,0	16	0,9	1822	100,0	13	0,7	1,26		Algorithm converged.	0,60	2,63	0,002		Algorithm converged.	-0,004	0,008	1,26		Algorithm converged.	0,61	2,61	0,5376		0,80		Algorithm converged.	0,38	1,65
	ECTROPION OF CERVIX	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ENDOMETRIAL HYPERPLASIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ENDOMETRIAL HYPERTROPHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ENDOMETRIAL THICKENING	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	ENDOMETRIOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ERECTILE DYSFUNCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GALACTORRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENITAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL PROLAPSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENITAL RASH	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENITAL TRACT INFLAMMATION	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	GENITAL ULCERATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		
	HEAVY MENSTRUAL BLEEDING	n/a	1783	100,0	8	0,4	1822	100,0	4	0,2	2,05		Algorithm converged.	0,62	6,81	0,002		Algorithm converged.	-0,001	0,006		2,04		Algorithm converged.	0,62	6,77	0,2424		0,49		Algorithm converged.	0,15	1,62		
	INTERMENSTRUAL BLEEDING	n/a	1783	100,0	7	0,4	1822	100,0	11	0,6	0,65		Algorithm converged.	0,25	1,68	-0,002		Algorithm converged.	-0,007	0,002		0,65		Algorithm converged.	0,25	1,67	0,3723		1,54		Algorithm converged.	0,60	3,96		
	MENOMETRORRHAGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENOPAUSAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENOPAUSAL SYMPTOMS	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005	2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95
	MENSTRUAL DISORDER	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003	0,88		Algorithm converged.	0,29	2,60	0,8114		1,14		Algorithm converged.	0,38	3,39
	MENSTRUATION IRREGULAR	n/a	1783	100,0	30	1,7	1822	100,0	37	2,0	0,83		Algorithm converged.	0,51	1,34	-0,003		Algorithm converged.	-0,012	0,005	0,83		Algorithm converged.	0,51	1,34	0,4397		1,21		Algorithm converged.	0,75	1,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NIPPLE EXUDATE BLOODY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OLIGOMENORRHOEA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OVARIAN CYST	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	PELVIC CYST	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PELVIC DISCOMFORT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	PELVIC FLOOR MUSCLE WEAKNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	PELVIC PAIN	n/a	1783	100,0	3	0,2	1822	100,0	15	0,8	0,20		Algorithm converged.	0,06	0,70	-0,007		Algorithm converged.	-0,011	-0,002		0,20		Algorithm converged.	0,06	0,70	0,0119			4,89		Algorithm converged.	1,42	16,87	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERINEAL ERYTHEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERINEAL PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PERINEAL ULCERATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PREMATURE MENOPAUSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURITUS GENITAL	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	REPRODUCTIVE TRACT DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RETRACTED NIPPLE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UTERINE HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UTERINE POLYP	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL CYST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL DISCHARGE	n/a	1783	100,0	29	1,6	1822	100,0	21	1,2	1,42		Algorithm converged.	0,81	2,50	0,005		Algorithm converged.	-0,003	0,012	1,41		Algorithm converged.	0,81	2,47	0,2262		0,71		Algorithm converged.	0,41	1,24
	VAGINAL HAEMORRHAGE	n/a	1783	100,0	13	0,7	1822	100,0	17	0,9	0,78		Algorithm converged.	0,38	1,61	-0,002		Algorithm converged.	-0,008	0,004	0,78		Algorithm converged.	0,38	1,60	0,5015		1,28		Algorithm converged.	0,62	2,63
	VAGINAL LESION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VAGINAL OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	VULVAL DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAL ULCERATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAR EROSION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL BURNING SENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	VULVOVAGINAL DISCOMFORT	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL DRYNESS	n/a	1783	100,0	65	3,6	1822	100,0	64	3,5	1,04		Algorithm converged.	0,73	1,48	0,001		Algorithm converged.	-0,011	0,013	1,04		Algorithm converged.	0,74	1,46	0,8299		0,96		Algorithm converged.	0,69	1,35
	VULVOVAGINAL ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL INFLAMMATION	n/a	1783	100,0	10	0,6	1822	100,0	8	0,4	1,28		Algorithm converged.	0,50	3,25	0,001		Algorithm converged.	-0,003	0,006	1,28		Algorithm converged.	0,51	3,23	0,6049		0,78		Algorithm converged.	0,31	1,98
	VULVOVAGINAL PAIN	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	VULVOVAGINAL PRURITUS	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL RASH	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	849	47,6	1822	100,0	791	43,4	1,18		Algorithm converged.	1,04	1,35	0,042		Algorithm converged.	0,010	0,075	1,10		Algorithm converged.	1,02	1,18	0,0114		0,91		Algorithm converged.	0,85	0,98
	ACUTE RESPIRATORY DISTRESS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALLERGIC SINUSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APHONIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002		0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	APNOEA	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	ASTHMA	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003		0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ATELECTASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BRONCHIAL DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHIAL HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BRONCHIECTASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHOPNEUMOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BRONCHOSPASM	n/a	1783	100,0	2	0,1	1822	100,0	8	0,4	0,25		Algorithm converged.	0,05	1,20	-0,003		Algorithm converged.	-0,007	0,000	0,26		Algorithm converged.	0,05	1,20	0,0840		3,91		Algorithm converged.	0,83	18,41
	BRONCHOSTENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATARRH	n/a	1783	100,0	9	0,5	1822	100,0	8	0,4	1,15		Algorithm converged.	0,44	2,99	0,001		Algorithm converged.	-0,004	0,005	1,15		Algorithm converged.	0,44	2,97	0,7737		0,87		Algorithm converged.	0,34	2,25

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CHOKING SENSATION	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	COUGH	n/a	1783	100,0	285	16,0	1822	100,0	283	15,5	1,03		Algorithm converged.	0,86	1,24	0,005		Algorithm converged.	-0,019	0,028	1,03		Algorithm converged.	0,88	1,20	0,7096		0,97		Algorithm converged.	0,84	1,13	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY THROAT	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	DYSAESTHESIA PHARYNX	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DYSPHONIA	n/a	1783	100,0	25	1,4	1822	100,0	17	0,9	1,51		Algorithm converged.	0,81	2,81	0,005		Algorithm converged.	-0,002	0,012	1,50		Algorithm converged.	0,81	2,77	0,1926		0,67		Algorithm converged.	0,36	1,23
	DYSPNOEA	n/a	1783	100,0	194	10,9	1822	100,0	204	11,2	0,97		Algorithm converged.	0,79	1,19	-0,003		Algorithm converged.	-0,024	0,017	0,97		Algorithm converged.	0,81	1,17	0,7622		1,03		Algorithm converged.	0,85	1,24
	DYSPNOEA EXERTIONAL	n/a	1783	100,0	23	1,3	1822	100,0	33	1,8	0,71		Algorithm converged.	0,41	1,21	-0,005		Algorithm converged.	-0,013	0,003	0,71		Algorithm converged.	0,42	1,21	0,2081		1,40		Algorithm converged.	0,83	2,38
	EPISTAXIS	n/a	1783	100,0	304	17,0	1822	100,0	238	13,1	1,37		Algorithm converged.	1,14	1,64	0,040		Algorithm converged.	0,017	0,063	1,31		Algorithm converged.	1,12	1,53	0,0009		0,77		Algorithm converged.	0,66	0,90
	HAEMOPTYSIS	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	HICCUPS	n/a	1783	100,0	4	0,2	1822	100,0	9	0,5	0,45		Algorithm converged.	0,14	1,47	-0,003		Algorithm converged.	-0,007	0,001	0,45		Algorithm converged.	0,14	1,47	0,1883		2,20		Algorithm converged.	0,68	7,14
	HYPERVENTILATION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOXIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTERSTITIAL LUNG DISEASE	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	LARYNGEAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LARYNGEAL INFLAMMATION	n/a	1783	100,0	2	0,1	1822	100,0	7	0,4	0,29		Algorithm converged.	0,06	1,40	-0,003		Algorithm converged.	-0,006	0,001	0,29		Algorithm converged.	0,06	1,40	0,1243		3,43		Algorithm converged.	0,71	16,46

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	LARYNGEAL OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63	
	LARYNGEAL PAIN	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002		0,51		Algorithm converged.	0,09	2,79	0,4378			1,96		Algorithm converged.	0,36	10,67	
	LOWER RESPIRATORY TRACT CONGESTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG CONSOLIDATION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LUNG DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	LUNG INFILTRATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASAL CONGESTION	n/a	1783	100,0	36	2,0	1822	100,0	48	2,6	0,76		Algorithm converged.	0,49	1,18	-0,006		Algorithm converged.	-0,016	0,004	0,77		Algorithm converged.	0,50	1,17	0,2222		1,30		Algorithm converged.	0,85	2,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL CRUSTING	n/a	1783	100,0	7	0,4	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL DISCOMFORT	n/a	1783	100,0	12	0,7	1822	100,0	9	0,5	1,36		Algorithm converged.	0,57	3,25	0,002		Algorithm converged.	-0,003	0,007	1,36		Algorithm converged.	0,58	3,23	0,4818		0,73		Algorithm converged.	0,31	1,74
	NASAL DRYNESS	n/a	1783	100,0	40	2,2	1822	100,0	27	1,5	1,53		Algorithm converged.	0,93	2,50	0,008		Algorithm converged.	-0,001	0,016	1,51		Algorithm converged.	0,93	2,46	0,0930		0,66		Algorithm converged.	0,41	1,07
	NASAL INFLAMMATION	n/a	1783	100,0	17	1,0	1822	100,0	13	0,7	1,34		Algorithm converged.	0,65	2,77	0,002		Algorithm converged.	-0,004	0,008	1,34		Algorithm converged.	0,65	2,74	0,4295		0,75		Algorithm converged.	0,36	1,54
	NASAL MUCOSAL DISORDER	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	NASAL OBSTRUCTION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL OEDEMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL POLYPS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL SEPTUM ULCERATION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL TURBINATE HYPERTROPHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.5818 6164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASAL ULCER	n/a	1783	100,0	11	0,6	1822	100,0	4	0,2	2,82		Algorithm converged.	0,90	8,88	0,004		Algorithm converged.	0,000	0,008		2,81		Algorithm converged.	0,90	8,81	0,0763		0,36		Algorithm converged.	0,11	1,12
	OROPHARYNGEAL DISCOMFORT	n/a	1783	100,0	4	0,2	1822	100,0	7	0,4	0,58		Algorithm converged.	0,17	1,99	-0,002		Algorithm converged.	-0,005	0,002		0,58		Algorithm converged.	0,17	1,99	0,3900		1,71		Algorithm converged.	0,50	5,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	OROPHARYNGEAL PAIN	n/a	1783	100,0	168	9,4	1822	100,0	135	7,4	1,30		Algorithm converged.	1,03	1,65	0,020		Algorithm converged.	0,002	0,038	1,27		Algorithm converged.	1,02	1,58	0,0299		0,79		Algorithm converged.	0,63	0,98	
	OROPHARYNGEAL PLAQUE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ORTHOPNOEA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAINFUL RESPIRATION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARANASAL SINUS DISCOMFORT	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	PARANASAL SINUS HYPERSECRETION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PHARYNGEAL ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PHARYNGEAL INFLAMMATION	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGEAL SWELLING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL EFFUSION	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	PLEURAL THICKENING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURITIC PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMONITIS	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	PNEUMOTHORAX	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PRODUCTIVE COUGH	n/a	1783	100,0	19	1,1	1822	100,0	17	0,9	1,14		Algorithm converged.	0,59	2,21	0,001		Algorithm converged.	-0,005	0,008	1,14		Algorithm converged.	0,60	2,19	0,6892		0,88		Algorithm converged.	0,46	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY CONGESTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PULMONARY EMBOLISM	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005	2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95
	PULMONARY FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PULMONARY HYPERTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RALES	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	REFLUX LARYNGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RESPIRATORY DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT CONGESTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	RESPIRATORY TRACT IRRITATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RHINALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHINITIS ALLERGIC	n/a	1783	100,0	27	1,5	1822	100,0	29	1,6	0,95		Algorithm converged.	0,56	1,61	-0,001		Algorithm converged.	-0,009	0,007		0,95		Algorithm converged.	0,57	1,60	0,8511		1,05		Algorithm converged.	0,62	1,77
	RHINORRHOEA	n/a	1783	100,0	142	8,0	1822	100,0	93	5,1	1,61		Algorithm converged.	1,23	2,11	0,029		Algorithm converged.	0,012	0,045		1,56		Algorithm converged.	1,21	2,01	0,0006		0,64		Algorithm converged.	0,50	0,83
	SINUS CONGESTION	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005		1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31
	SINUS DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	SINUS PAIN	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002		0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	SLEEP APNOEA SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SNEEZING	n/a	1783	100,0	7	0,4	1822	100,0	5	0,3	1,43		Algorithm converged.	0,45	4,52	0,001		Algorithm converged.	-0,003	0,005		1,43		Algorithm converged.	0,45	4,50	0,5402		0,70		Algorithm converged.	0,22	2,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPUTUM INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STRIDOR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYPNOEA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	THROAT IRRITATION	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROAT TIGHTNESS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	TRACHEAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER RESPIRATORY TRACT CONGESTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER RESPIRATORY TRACT INFLAMMATION	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	UPPER RESPIRATORY TRACT IRRITATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER-AIRWAY COUGH SYNDROME	n/a	1783	100,0	20	1,1	1822	100,0	17	0,9	1,20		Algorithm converged.	0,63	2,31	0,002		Algorithm converged.	-0,005	0,008	1,20		Algorithm converged.	0,63	2,29	0,5747		0,83		Algorithm converged.	0,44	1,58
	VOCAL CORD INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHEEZING	n/a	1783	100,0	4	0,2	1822	100,0	6	0,3	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,004	0,002	0,68		Algorithm converged.	0,19	2,41	0,5516		1,47		Algorithm converged.	0,41	5,19
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	1566	87,8	1822	100,0	1534	84,2	1,35		Algorithm converged.	1,12	1,64	0,036		Algorithm converged.	0,014	0,059	1,04		Algorithm converged.	1,02	1,07	0,0017		0,96		Algorithm converged.	0,93	0,98
	ACNE	n/a	1783	100,0	23	1,3	1822	100,0	21	1,2	1,12		Algorithm converged.	0,62	2,03	0,001		Algorithm converged.	-0,006	0,009	1,12		Algorithm converged.	0,62	2,01	0,7074		0,89		Algorithm converged.	0,50	1,61
	ACTINIC KERATOSIS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALOPECIA	n/a	1783	100,0	1206	67,6	1822	100,0	1229	67,5	1,01		Algorithm converged.	0,88	1,16	0,002		Algorithm converged.	-0,029	0,032	1,00		Algorithm converged.	0,96	1,05	0,9053		1,00		Algorithm converged.	0,95	1,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALOPECIA AREATA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ALOPECIA TOTALIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ANGIOEDEMA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLISTER	n/a	1783	100,0	12	0,7	1822	100,0	7	0,4	1,76		Algorithm converged.	0,69	4,47	0,003		Algorithm converged.	-0,002	0,008	1,75		Algorithm converged.	0,69	4,44	0,2373		0,57		Algorithm converged.	0,23	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BLISTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BUTTERFLY RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLD SWEAT	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMAL CYST	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	DERMATITIS	n/a	1783	100,0	81	4,5	1822	100,0	73	4,0	1,14		Algorithm converged.	0,83	1,58	0,005		Algorithm converged.	-0,008	0,019	1,13		Algorithm converged.	0,83	1,55	0,4263		0,88		Algorithm converged.	0,65	1,20
	DERMATITIS ACNEIFORM	n/a	1783	100,0	62	3,5	1822	100,0	33	1,8	1,95		Algorithm converged.	1,27	2,99	0,017		Algorithm converged.	0,006	0,027	1,92		Algorithm converged.	1,26	2,91	0,0022		0,52		Algorithm converged.	0,34	0,79
	DERMATITIS ALLERGIC	n/a	1783	100,0	10	0,6	1822	100,0	10	0,5	1,02		Algorithm converged.	0,42	2,46	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,43	2,45	0,9613		0,98		Algorithm converged.	0,41	2,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DERMATITIS ATOPIC	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS BULLOUS	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	DERMATITIS CONTACT	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3	1,36		Algorithm converged.	0,47	3,94	0,001		Algorithm converged.	-0,003	0,005	1,36		Algorithm converged.	0,47	3,92	0,5661		0,73		Algorithm converged.	0,26	2,11
	DERMATITIS DIAPER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.37850919 4 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DERMATITIS EXFOLIATIVE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	DERMATITIS EXFOLIATIVE GENERALISED	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004		2,04		Algorithm converged.	0,37	11,14	0,4088			0,49		Algorithm converged.	0,09	2,67	
	DRUG ERUPTION	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005		1,53		Algorithm converged.	0,43	5,42	0,5076			0,65		Algorithm converged.	0,18	2,31	
	DRY SKIN	n/a	1783	100,0	227	12,7	1822	100,0	190	10,4	1,25		Algorithm converged.	1,02	1,54	0,023		Algorithm converged.	0,002	0,044		1,22		Algorithm converged.	1,02	1,46	0,0310			0,82		Algorithm converged.	0,68	0,98	
	DYSHIDROTIC ECZEMA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593			0,49		Algorithm converged.	0,04	5,39	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECCHYMOSIS	n/a	1783	100,0	5	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ECZEMA	n/a	1783	100,0	33	1,9	1822	100,0	20	1,1	1,70		Algorithm converged.	0,97	2,97	0,008		Algorithm converged.	0,000	0,015	1,69		Algorithm converged.	0,97	2,93	0,0634		0,59		Algorithm converged.	0,34	1,03
	ECZEMA ASTEATOTIC	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	EPIDERMOLYSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ERYTHEMA	n/a	1783	100,0	189	10,6	1822	100,0	170	9,3	1,15		Algorithm converged.	0,93	1,43	0,013		Algorithm converged.	-0,007	0,032	1,14		Algorithm converged.	0,93	1,38	0,2034		0,88		Algorithm converged.	0,72	1,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ERYTHEMA MULTIFORME	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	ERYTHEMA NODOSUM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ERYTHROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXCESSIVE GRANULATION TISSUE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXFOLIATIVE RASH	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	HAIR GROWTH ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAND DERMATITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HANGNAIL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HIRSUTISM	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	HYPERHIDROSIS	n/a	1783	100,0	15	0,8	1822	100,0	16	0,9	0,96		Algorithm converged.	0,47	1,94	0,000		Algorithm converged.	-0,006	0,006	0,96		Algorithm converged.	0,48	1,93	0,9046		1,04		Algorithm converged.	0,52	2,10
	HYPERKERATOSIS	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRICHOSIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGROWING NAIL	n/a	1783	100,0	11	0,6	1822	100,0	7	0,4	1,61		Algorithm converged.	0,62	4,16	0,002		Algorithm converged.	-0,002	0,007	1,61		Algorithm converged.	0,62	4,13	0,3261		0,62		Algorithm converged.	0,24	1,60
	INTERTRIGO	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	ITCHING SCAR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LICHEN PLANUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIVEDO RETICULARIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MACULE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MADAROSIS	n/a	1783	100,0	7	0,4	1822	100,0	4	0,2	1,79		Algorithm converged.	0,52	6,13	0,002		Algorithm converged.	-0,002	0,005	1,79		Algorithm converged.	0,52	6,10	0,3531		0,56		Algorithm converged.	0,16	1,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MECHANICAL URTICARIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MILIARIA	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	NAIL BED BLEEDING	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL BED DISORDER	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL BED TENDERNESS	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	NAIL DISCOLOURATION	n/a	1783	100,0	136	7,6	1822	100,0	141	7,7	0,98		Algorithm converged.	0,77	1,26	-0,001		Algorithm converged.	-0,018	0,016	0,99		Algorithm converged.	0,79	1,24	0,9003		1,01		Algorithm converged.	0,81	1,27
	NAIL DISCOMFORT	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01
	NAIL DISORDER	n/a	1783	100,0	221	12,4	1822	100,0	204	11,2	1,12		Algorithm converged.	0,92	1,37	0,012		Algorithm converged.	-0,009	0,033	1,11		Algorithm converged.	0,93	1,32	0,2649		0,90		Algorithm converged.	0,76	1,08
	NAIL DYSTROPHY	n/a	1783	100,0	13	0,7	1822	100,0	18	1,0	0,74		Algorithm converged.	0,36	1,51	-0,003		Algorithm converged.	-0,009	0,003	0,74		Algorithm converged.	0,36	1,50	0,4019		1,35		Algorithm converged.	0,67	2,76
	NAIL GROWTH ABNORMAL	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	NAIL PIGMENTATION	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL RIDGING	n/a	1783	100,0	41	2,3	1822	100,0	35	1,9	1,20		Algorithm converged.	0,76	1,90	0,004		Algorithm converged.	-0,006	0,013	1,20		Algorithm converged.	0,77	1,87	0,4296		0,84		Algorithm converged.	0,53	1,31
	NAIL TOXICITY	n/a	1783	100,0	53	3,0	1822	100,0	36	2,0	1,52		Algorithm converged.	0,99	2,33	0,010		Algorithm converged.	0,000	0,020	1,50		Algorithm converged.	0,99	2,29	0,0556		0,66		Algorithm converged.	0,44	1,01
	NEURODERMATITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NIGHT SWEATS	n/a	1783	100,0	18	1,0	1822	100,0	23	1,3	0,80		Algorithm converged.	0,43	1,48	-0,003		Algorithm converged.	-0,009	0,004	0,80		Algorithm converged.	0,43	1,48	0,4751		1,25		Algorithm converged.	0,68	2,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NODULAR RASH	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ONYCHALGIA	n/a	1783	100,0	16	0,9	1822	100,0	13	0,7	1,26		Algorithm converged.	0,60	2,63	0,002		Algorithm converged.	-0,004	0,008	1,26		Algorithm converged.	0,61	2,61	0,5376		0,80		Algorithm converged.	0,38	1,65
	ONYCHOCLASIS	n/a	1783	100,0	26	1,5	1822	100,0	26	1,4	1,02		Algorithm converged.	0,59	1,77	0,000		Algorithm converged.	-0,007	0,008	1,02		Algorithm converged.	0,60	1,75	0,9374		0,98		Algorithm converged.	0,57	1,68
	ONYCHOLYSIS	n/a	1783	100,0	54	3,0	1822	100,0	71	3,9	0,77		Algorithm converged.	0,54	1,10	-0,009		Algorithm converged.	-0,021	0,003	0,78		Algorithm converged.	0,55	1,10	0,1555		1,29		Algorithm converged.	0,91	1,82
	ONYCHOMADESIS	n/a	1783	100,0	80	4,5	1822	100,0	73	4,0	1,13		Algorithm converged.	0,81	1,56	0,005		Algorithm converged.	-0,008	0,018	1,12		Algorithm converged.	0,82	1,53	0,4748		0,89		Algorithm converged.	0,65	1,22
	ONYCHOMALACIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PAIN OF SKIN	n/a	1783	100,0	20	1,1	1822	100,0	13	0,7	1,58		Algorithm converged.	0,78	3,18	0,004		Algorithm converged.	-0,002	0,010	1,57		Algorithm converged.	0,78	3,15	0,2021		0,64		Algorithm converged.	0,32	1,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PALMAR ERYTHEMA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	n/a	1783	100,0	158	8,9	1822	100,0	112	6,1	1,48		Algorithm converged.	1,15	1,91	0,027		Algorithm converged.	0,010	0,044	1,44		Algorithm converged.	1,14	1,82	0,0021		0,69		Algorithm converged.	0,55	0,88
	PAPULE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PEAU D'ORANGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PETECHIAE	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004		4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	PHOTOSENSITIVITY REACTION	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005		1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31
	PIGMENTATION DISORDER	n/a	1783	100,0	9	0,5	1822	100,0	11	0,6	0,84		Algorithm converged.	0,35	2,02	-0,001		Algorithm converged.	-0,006	0,004		0,84		Algorithm converged.	0,35	2,01	0,6896		1,20		Algorithm converged.	0,50	2,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PITYRIASIS ROSEA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLANTAR ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURIGO	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	PRURITUS	n/a	1783	100,0	261	14,6	1822	100,0	163	8,9	1,75		Algorithm converged.	1,42	2,15	0,057		Algorithm converged.	0,036	0,078	1,64		Algorithm converged.	1,36	1,97	<.0001		0,61		Algorithm converged.	0,51	0,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSORIASIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	PURPURA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	RASH	n/a	1783	100,0	461	25,9	1822	100,0	368	20,2	1,38		Algorithm converged.	1,18	1,61	0,057		Algorithm converged.	0,029	0,084	1,28		Algorithm converged.	1,13	1,44	<.0001		0,78		Algorithm converged.	0,69	0,88
	RASH ERYTHEMATOUS	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	RASH FOLLICULAR	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH MACULAR	n/a	1783	100,0	13	0,7	1822	100,0	10	0,5	1,33		Algorithm converged.	0,58	3,04	0,002		Algorithm converged.	-0,003	0,007	1,33		Algorithm converged.	0,58	3,02	0,4982		0,75		Algorithm converged.	0,33	1,71
	RASH MACULO-PAPULAR	n/a	1783	100,0	60	3,4	1822	100,0	44	2,4	1,41		Algorithm converged.	0,95	2,09	0,010		Algorithm converged.	-0,001	0,020	1,39		Algorithm converged.	0,95	2,04	0,0899		0,72		Algorithm converged.	0,49	1,05
	RASH PAPULAR	n/a	1783	100,0	6	0,3	1822	100,0	4	0,2	1,53		Algorithm converged.	0,43	5,45	0,001		Algorithm converged.	-0,002	0,005	1,53		Algorithm converged.	0,43	5,42	0,5076		0,65		Algorithm converged.	0,18	2,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH PRURITIC	n/a	1783	100,0	12	0,7	1822	100,0	15	0,8	0,82		Algorithm converged.	0,38	1,75	-0,002		Algorithm converged.	-0,007	0,004		0,82		Algorithm converged.	0,38	1,74	0,6015		1,22		Algorithm converged.	0,57	2,61
	RASH VESICULAR	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ROSACEA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SCAB	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	SCAR PAIN	n/a	1783	100,0	14	0,8	1822	100,0	9	0,5	1,59		Algorithm converged.	0,69	3,69	0,003		Algorithm converged.	-0,002	0,008		1,59		Algorithm converged.	0,69	3,66	0,2766		0,63		Algorithm converged.	0,27	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEBORRHOEA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEBORRHOEIC DERMATITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SENSITIVE SKIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SKIN ATROPHY	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	SKIN BURNING SENSATION	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN DEPIGMENTATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN DISCOLOURATION	n/a	1783	100,0	11	0,6	1822	100,0	10	0,5	1,12		Algorithm converged.	0,48	2,66	0,001		Algorithm converged.	-0,004	0,006	1,12		Algorithm converged.	0,48	2,64	0,7884		0,89		Algorithm converged.	0,38	2,09
	SKIN DISORDER	n/a	1783	100,0	15	0,8	1822	100,0	12	0,7	1,28		Algorithm converged.	0,60	2,74	0,002		Algorithm converged.	-0,004	0,007	1,28		Algorithm converged.	0,60	2,72	0,5258		0,78		Algorithm converged.	0,37	1,67
	SKIN EROSION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	SKIN EXFOLIATION	n/a	1783	100,0	30	1,7	1822	100,0	28	1,5	1,10		Algorithm converged.	0,65	1,84	0,001		Algorithm converged.	-0,007	0,010	1,09		Algorithm converged.	0,66	1,82	0,7281		0,91		Algorithm converged.	0,55	1,52
	SKIN FISSURES	n/a	1783	100,0	26	1,5	1822	100,0	24	1,3	1,11		Algorithm converged.	0,63	1,94	0,001		Algorithm converged.	-0,006	0,009	1,11		Algorithm converged.	0,64	1,92	0,7176		0,90		Algorithm converged.	0,52	1,57
	SKIN HYPERPIGMENTATION	n/a	1783	100,0	79	4,4	1822	100,0	69	3,8	1,18		Algorithm converged.	0,85	1,64	0,006		Algorithm converged.	-0,007	0,019	1,17		Algorithm converged.	0,85	1,61	0,3307		0,85		Algorithm converged.	0,62	1,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	SKIN HYPERTROPHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SKIN HYPOPIGMENTATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN INDURATION	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428841 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN IRRITATION	n/a	1783	100,0	12	0,7	1822	100,0	8	0,4	1,54		Algorithm converged.	0,63	3,77	0,002		Algorithm converged.	-0,003	0,007	1,53		Algorithm converged.	0,63	3,74	0,3481		0,65		Algorithm converged.	0,27	1,59
	SKIN LESION	n/a	1783	100,0	13	0,7	1822	100,0	8	0,4	1,67		Algorithm converged.	0,69	4,03	0,003		Algorithm converged.	-0,002	0,008	1,66		Algorithm converged.	0,69	4,00	0,2578		0,60		Algorithm converged.	0,25	1,45
	SKIN MASS	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
	SKIN ODOUR ABNORMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE									
	SKIN OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63									
	SKIN PLAQUE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE									
	SKIN REACTION	n/a	1783	100,0	6	0,3	1822	100,0	5	0,3	1,23		Algorithm converged.	0,37	4,03	0,001		Algorithm converged.	-0,003	0,004	1,23		Algorithm converged.	0,37	4,01	0,7359		0,82		Algorithm converged.	0,25	2,67									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	SKIN SWELLING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	SKIN TIGHTNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	SKIN TOXICITY	n/a	1783	100,0	18	1,0	1822	100,0	12	0,7	1,54		Algorithm converged.	0,74	3,20	0,004		Algorithm converged.	-0,002	0,009	1,53		Algorithm converged.	0,74	3,17	0,2499		0,65		Algorithm converged.	0,32	1,35						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN ULCER	n/a	1783	100,0	16	0,9	1822	100,0	9	0,5	1,82		Algorithm converged.	0,80	4,14	0,004		Algorithm converged.	-0,001	0,009	1,82		Algorithm converged.	0,80	4,10	0,1506		0,55		Algorithm converged.	0,24	1,24
	SKIN WRINKLING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SPIDER NAEVUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TELANGIECTASIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TOXIC EPIDERMAL NECROLYSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	TOXIC SKIN ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001		0,51		Algorithm converged.	0,05	5,63	0,5834			1,96		Algorithm converged.	0,18	21,57	
	UMBILICAL ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URTICARIA	n/a	1783	100,0	28	1,6	1822	100,0	29	1,6	0,99		Algorithm converged.	0,58	1,66	0,000		Algorithm converged.	-0,008	0,008	0,99		Algorithm converged.	0,59	1,65	0,9592		1,01		Algorithm converged.	0,61	1,70
	URTICARIA CONTACT	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	URTICARIA PAPULAR	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	XERODERMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
SOCIAL CIRCUMSTANCE	-Total	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INADEQUATE DIET	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENOPAUSE	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
SURGICAL AND MEDICAL PROCEDURE	-Total	n/a	1783	100,0	8	0,4	1822	100,0	11	0,6	0,74		Algorithm converged.	0,30	1,85	-0,002		Algorithm converged.	-0,006	0,003	0,74		Algorithm converged.	0,30	1,84	0,5219		1,35		Algorithm converged.	0,54	3,34
	ASTRINGENT THERAPY	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST RECONSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST TUMOUR EXCISION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CENTRAL VENOUS CATHETER REMOVAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CENTRAL VENOUS CATHETERISATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DENTAL CARE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HOSPITALISATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SINUS OPERATION	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH RESTORATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
VASCULAR DISORDER	-Total	n/a	1783	100,0	630	35,3	1822	100,0	676	37,1	0,93		Algorithm converged.	0,81	1,06	-0,018		Algorithm converged.	-0,049	0,014		0,95		Algorithm converged.	0,87	1,04	0,2696		1,05		Algorithm converged.	0,96	1,15
	ANGIOPATHY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANGIOSCLEROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	AORTIC DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTERIOSCLEROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AXILLARY VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD PRESSURE FLUCTUATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOODY DISCHARGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CIRCULATORY COLLAPSE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEEP VEIN THROMBOSIS	n/a	1783	100,0	7	0,4	1822	100,0	8	0,4	0,89		Algorithm converged.	0,32	2,47	0,000		Algorithm converged.	-0,005	0,004	0,89		Algorithm converged.	0,32	2,46	0,8285		1,12		Algorithm converged.	0,41	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY GANGRENE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	EMBOLISM	n/a	1783	100,0	12	0,7	1822	100,0	4	0,2	3,08		Algorithm converged.	0,99	9,57	0,005		Algorithm converged.	0,000	0,009		3,07		Algorithm converged.	0,99	9,49	0,0519			0,33		Algorithm converged.	0,11	1,01
	EMBOLISM VENOUS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003		3,07		Algorithm converged.	0,32	29,44	0,3318			0,33		Algorithm converged.	0,03	3,13
	FLUSHING	n/a	1783	100,0	59	3,3	1822	100,0	59	3,2	1,02		Algorithm converged.	0,71	1,48	0,001		Algorithm converged.	-0,011	0,012		1,02		Algorithm converged.	0,72	1,46	0,9049			0,98		Algorithm converged.	0,69	1,40
	HAEMATOMA	n/a	1783	100,0	7	0,4	1822	100,0	7	0,4	1,02		Algorithm converged.	0,36	2,92	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,36	2,91	0,9676			0,98		Algorithm converged.	0,34	2,78
	HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397			0,65		Algorithm converged.	0,11	3,90
	HOT FLUSH	n/a	1783	100,0	333	18,7	1822	100,0	353	19,4	0,96		Algorithm converged.	0,81	1,13	-0,007		Algorithm converged.	-0,033	0,019		0,96		Algorithm converged.	0,84	1,10	0,5936			1,04		Algorithm converged.	0,91	1,19
	HYPERAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002		0,68		Algorithm converged.	0,11	4,07	0,6739			1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSION	n/a	1783	100,0	74	4,2	1822	100,0	97	5,3	0,77		Algorithm converged.	0,56	1,05	-0,012		Algorithm converged.	-0,026	0,002	0,78		Algorithm converged.	0,58	1,05	0,0985		1,28		Algorithm converged.	0,95	1,72
	HYPERTENSIVE CRISIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOTENSION	n/a	1783	100,0	40	2,2	1822	100,0	30	1,6	1,37		Algorithm converged.	0,85	2,21	0,006		Algorithm converged.	-0,003	0,015	1,36		Algorithm converged.	0,85	2,18	0,1960		0,73		Algorithm converged.	0,46	1,17
	INFERIOR VENA CAVA DILATATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERNAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	JUGULAR VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOCELE	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	LYMPHOEDEMA	n/a	1783	100,0	124	7,0	1822	100,0	155	8,5	0,80		Algorithm converged.	0,63	1,03	-0,016		Algorithm converged.	-0,033	0,002	0,82		Algorithm converged.	0,65	1,03	0,0818		1,22		Algorithm converged.	0,97	1,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHORRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOSTASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORTHOSTATIC HYPOTENSION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PALLOR	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003		3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL COLDNESS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PERIPHERAL VASCULAR DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERIPHERAL VENOUS DISEASE	n/a	1783	100,0	5	0,3	1822	100,0	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,30	3,52	0,9727		0,98		Algorithm converged.	0,28	3,37
	PHLEBITIS	n/a	1783	100,0	31	1,7	1822	100,0	36	2,0	0,88		Algorithm converged.	0,54	1,43	-0,002		Algorithm converged.	-0,011	0,006	0,88		Algorithm converged.	0,55	1,42	0,5983		1,14		Algorithm converged.	0,71	1,83
	PHLEBITIS SUPERFICIAL	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PREHYPERTENSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCLAVIAN VEIN THROMBOSIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	SUPERFICIAL VEIN THROMBOSIS	n/a	1783	100,0	2	0,1	1822	100,0	7	0,4	0,29		Algorithm converged.	0,06	1,40	-0,003		Algorithm converged.	-0,006	0,001	0,29		Algorithm converged.	0,06	1,40	0,1243		3,43		Algorithm converged.	0,71	16,46
	SUPERIOR VENA CAVA OCCLUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	SUPERIOR VENA CAVA SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	THROMBOPHLEBITIS	n/a	1783	100,0	6	0,3	1822	100,0	8	0,4	0,77		Algorithm converged.	0,27	2,21	-0,001		Algorithm converged.	-0,005	0,003	0,77		Algorithm converged.	0,27	2,20	0,6216		1,30		Algorithm converged.	0,45	3,75	
	THROMBOSED VARICOSE VEIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	n/a	1783	100,0	6	0,3	1822	100,0	15	0,8	0,41		Algorithm converged.	0,16	1,05	-0,005		Algorithm converged.	-0,010	0,000	0,41		Algorithm converged.	0,16	1,05	0,0634		2,45		Algorithm converged.	0,95	6,29
	VARICOSE VEIN	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	VASCULAR PAIN	n/a	1783	100,0	12	0,7	1822	100,0	8	0,4	1,54		Algorithm converged.	0,63	3,77	0,002		Algorithm converged.	-0,003	0,007	1,53		Algorithm converged.	0,63	3,74	0,3481		0,65		Algorithm converged.	0,27	1,59
	VASCULAR RUPTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULITIS	n/a	1783	100,0	17	1,0	1822	100,0	16	0,9	1,09		Algorithm converged.	0,55	2,16	0,001		Algorithm converged.	-0,005	0,007	1,09		Algorithm converged.	0,55	2,14	0,8125		0,92		Algorithm converged.	0,47	1,82
	VASODILATATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VEIN DISCOLOURATION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS LIMB	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_ANYAE_S1.xls
05MAY2022 13:13

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	824	52,7	1601	87,9	758	47,3	1,24		Algorithm converged.	1,08	1,42	0,053		Algorithm converged.	0,019	0,088	1,11		Algorithm converged.	1,04	1,19	0,0027	0,0635	0,90		Algorithm converged.	0,84	0,96
		>= 65	219	12,3	118	53,9	221	12,1	127	57,5	0,86		Algorithm converged.	0,59	1,26	-0,036		Algorithm converged.	-0,129	0,057	0,94		Algorithm converged.	0,79	1,11	0,4496		1,07		Algorithm converged.	0,90	1,26
	AGRANULOCYTOSIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAEMIA	< 65	1564	87,7	427	27,3	1601	87,9	355	22,2	1,32		Algorithm converged.	1,12	1,55	0,051		Algorithm converged.	0,021	0,081	1,23		Algorithm converged.	1,09	1,39	0,0009	0,1405	0,81		Algorithm converged.	0,72	0,92
		>= 65	219	12,3	77	35,2	221	12,1	78	35,3	0,99		Algorithm converged.	0,67	1,47	-0,001		Algorithm converged.	-0,091	0,088	1,00		Algorithm converged.	0,77	1,28	0,9765		1,00		Algorithm converged.	0,78	1,29
	ANAEMIA MACROCYTIC	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE MARROW FAILURE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED INTRAVASCULAR COAGULATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHILIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHROPENIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	7	0,4	1601	87,9	5	0,3	1,44		Algorithm converged.	0,45	4,53	0,001		Algorithm converged.	-0,003	0,006	1,43		Algorithm converged.	0,46	4,51	0,5381	-	0,70		Algorithm converged.	0,22	2,19
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	181	11,6	1601	87,9	157	9,8	1,20		Algorithm converged.	0,96	1,51	0,018		Algorithm converged.	-0,004	0,039	1,18		Algorithm converged.	0,96	1,44	0,1082	0,3868	0,85		Algorithm converged.	0,69	1,04
		>= 65	219	12,3	31	14,2	221	12,1	33	14,9	0,94		Algorithm converged.	0,55	1,60	-0,008		Algorithm converged.	-0,074	0,058	0,95		Algorithm converged.	0,60	1,49	0,8173		1,05		Algorithm converged.	0,67	1,66
	GRANULOCYTOPENIA	< 65	1564	87,7	15	1,0	1601	87,9	19	1,2	0,81		Algorithm converged.	0,41	1,59	-0,002		Algorithm converged.	-0,009	0,005	0,81		Algorithm converged.	0,41	1,58	0,5353	-	1,24		Algorithm converged.	0,63	2,43
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMATOTOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBINAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERLEUKOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCREASED TENDENCY TO BRUISE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY ANAEMIA	< 65	1564	87,7	9	0,6	1601	87,9	2	0,1	4,63		Algorithm converged.	1,00	21,45	0,005		Algorithm converged.	0,000	0,009	4,61		Algorithm converged.	1,00	21,29	0,0505	-	0,22		Algorithm converged.	0,05	1,00
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	LEUKOCYTOSIS	< 65	1564	87,7	9	0,6	1601	87,9	6	0,4	1,54		Algorithm converged.	0,55	4,33	0,002		Algorithm converged.	-0,003	0,007	1,54		Algorithm converged.	0,55	4,30	0,4148	-	0,65		Algorithm converged.	0,23	1,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LEUKOPENIA	< 65	1564	87,7	155	9,9	1601	87,9	169	10,6	0,93		Algorithm converged.	0,74	1,17	-0,006		Algorithm converged.	-0,028	0,015	0,94		Algorithm converged.	0,76	1,15	0,5494	0,2266	1,07		Algorithm converged.	0,87	1,31
		>= 65	219	12,3	12	5,5	221	12,1	20	9,0	0,58		Algorithm converged.	0,28	1,22	-0,036		Algorithm converged.	-0,084	0,013	0,61		Algorithm converged.	0,30	1,21	0,1546		1,65		Algorithm converged.	0,83	3,30
	LYMPH NODE PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHADENITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHADENOPATHY	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020		2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOID TISSUE HYPERPLASIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOPENIA	< 65	1564	87,7	10	0,6	1601	87,9	10	0,6	1,02		Algorithm converged.	0,42	2,47	0,000		Algorithm converged.	-0,005	0,006	1,02		Algorithm converged.	0,43	2,45	0,9582	-	0,98		Algorithm converged.	0,41	2,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICROCYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	< 65	1564	87,7	8	0,5	1601	87,9	13	0,8	0,63		Algorithm converged.	0,26	1,52	-0,003		Algorithm converged.	-0,009	0,003	0,63		Algorithm converged.	0,26	1,52	0,3022	-	1,59		Algorithm converged.	0,66	3,82
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	< 65	1564	87,7	412	26,3	1601	87,9	380	23,7	1,15		Algorithm converged.	0,98	1,35	0,026		Algorithm converged.	-0,004	0,056	1,11		Algorithm converged.	0,98	1,25	0,0906	0,9928	0,90		Algorithm converged.	0,80	1,02
		>= 65	219	12,3	56	25,6	221	12,1	51	23,1	1,15		Algorithm converged.	0,74	1,77	0,025		Algorithm converged.	-0,055	0,105	1,11		Algorithm converged.	0,80	1,54	0,5424		0,90		Algorithm converged.	0,65	1,26
	NEUTROPHILIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	NORMOCHROMIC NORMOCYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCYTOPENIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	< 65	1564	87,7	61	3,9	1601	87,9	46	2,9	1,37		Algorithm converged.	0,93	2,02	0,010		Algorithm converged.	-0,002	0,023	1,36		Algorithm converged.	0,93	1,98	0,1115	0,0640	0,74		Algorithm converged.	0,51	1,07
		>= 65	219	12,3	14	6,4	221	12,1	21	9,5	0,65		Algorithm converged.	0,32	1,31	-0,031		Algorithm converged.	-0,082	0,019	0,67		Algorithm converged.	0,35	1,29	0,2320		1,49		Algorithm converged.	0,78	2,85
	THROMBOCYTOSIS	< 65	1564	87,7	8	0,5	1601	87,9	1	<0.1	8,23		Algorithm converged.	1,03	65,85	0,004		Algorithm converged.	0,001	0,008	8,19		Algorithm converged.	1,03	65,40	0,0473	-	0,12		Algorithm converged.	0,02	0,98
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	< 65	1564	87,7	175	11,2	1601	87,9	173	10,8	1,04		Algorithm converged.	0,83	1,30	0,004		Algorithm converged.	-0,018	0,026	1,04		Algorithm converged.	0,85	1,26	0,7302	0,3440	0,97		Algorithm converged.	0,79	1,18
		>= 65	219	12,3	33	15,1	221	12,1	25	11,3	1,39		Algorithm converged.	0,80	2,43	0,038		Algorithm converged.	-0,026	0,101	1,33		Algorithm converged.	0,82	2,16	0,2465		0,75		Algorithm converged.	0,46	1,22

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ANGINA PECTORIS	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AORTIC VALVE INCOMPETENCE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AORTIC VALVE SCLEROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTERIOSCLEROSIS CORONARY ARTERY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIAL FIBRILLATION	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	2	0,9	221	12,1	5	2,3	0,40		Algorithm converged.	0,08	2,07	-0,013		Algorithm converged.	-0,037	0,010	0,40		Algorithm converged.	0,08	2,06	0,2751		2,48		Algorithm converged.	0,49	12,63
	ATRIAL TACHYCARDIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIAL THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BIFASCICULAR BLOCK	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BUNDLE BRANCH BLOCK	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUNDLE BRANCH BLOCK LEFT	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUNDLE BRANCH BLOCK RIGHT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC ANEURYSM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC DISORDER	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1	5,13		Algorithm converged.	0,60	43,97	0,003		Algorithm converged.	0,000	0,006	5,12		Algorithm converged.	0,60	43,76	0,1359	-	0,20		Algorithm converged.	0,02	1,67
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC FAILURE	< 65	1564	87,7	16	1,0	1601	87,9	9	0,6	1,83		Algorithm converged.	0,81	4,15	0,005		Algorithm converged.	-0,002	0,011	1,82		Algorithm converged.	0,81	4,11	0,1492	0,7587	0,55		Algorithm converged.	0,24	1,24
		>= 65	219	12,3	9	4,1	221	12,1	4	1,8	2,32		Algorithm converged.	0,71	7,67	0,023		Algorithm converged.	-0,009	0,055	2,27		Algorithm converged.	0,71	7,26	0,1669		0,44		Algorithm converged.	0,14	1,41
	CARDIAC FAILURE CONGESTIVE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CARDIOMYOPATHY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIOVASCULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CARDIOVASCULAR INSUFFICIENCY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONDUCTION DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIASTOLIC DYSFUNCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTRASYSTOLES	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963341 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEART VALVE INCOMPETENCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE HEART DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LEFT VENTRICULAR DILATATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEFT VENTRICULAR DYSFUNCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEFT VENTRICULAR HYPERTROPHY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	METABOLIC CARDIOMYOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MITRAL VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE INCOMPETENCE	< 65	1564	87,7	4	0,3	1601	87,9	6	0,4	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,005	0,003	0,68		Algorithm converged.	0,19	2,41	0,5533	-	1,47		Algorithm converged.	0,41	5,18
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MITRAL VALVE PROLAPSE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	MYOCARDIAL ISCHAEMIA	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NODAL RHYTHM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALPITATIONS	< 65	1564	87,7	70	4,5	1601	87,9	77	4,8	0,93		Algorithm converged.	0,67	1,29	-0,003		Algorithm converged.	-0,018	0,011	0,93		Algorithm converged.	0,68	1,28	0,6556	-	1,07		Algorithm converged.	0,78	1,47
		>= 65	219	12,3	7	3,2	221	12,1	2	0,9	3,62		Algorithm converged.	0,74	17,60	0,023		Algorithm converged.	-0,004	0,049	3,53		Algorithm converged.	0,74	16,81	0,1130		0,28		Algorithm converged.	0,06	1,35
	PERICARDIAL EFFUSION	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PRINZMETAL ANGINA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS ARRHYTHMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SINUS BRADYCARDIA	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SINUS NODE DYSFUNCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS TACHYCARDIA	< 65	1564	87,7	10	0,6	1601	87,9	12	0,7	0,85		Algorithm converged.	0,37	1,98	-0,001		Algorithm converged.	-0,007	0,005	0,85		Algorithm converged.	0,37	1,97	0,7095	-	1,17		Algorithm converged.	0,51	2,71
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRESS CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SUPRAVENTRICULAR EXTRASYSTOLES	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SUPRAVENTRICULAR TACHYCARDIA	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TACHYARRHYTHMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA	< 65	1564	87,7	35	2,2	1601	87,9	29	1,8	1,24		Algorithm converged.	0,75	2,04	0,004		Algorithm converged.	-0,006	0,014	1,24		Algorithm converged.	0,76	2,01	0,3950	0,1815	0,81		Algorithm converged.	0,50	1,32
		>= 65	219	12,3	9	4,1	221	12,1	3	1,4	3,11		Algorithm converged.	0,83	11,66	0,028		Algorithm converged.	-0,003	0,058	3,03		Algorithm converged.	0,83	11,03	0,0932		0,33		Algorithm converged.	0,09	1,20
	TACHYCARDIA PAROXYSMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRICUSPID VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRICUSPID VALVE INCOMPETENCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR EXTRASYSTOLES	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR TACHYCARDIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTIC FIBROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHALANGEAL HYPOPLASIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PYLORIC STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TYPE V HYPERLIPIDAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
EAR AND LABYRINTH DISORDER	-Total	< 65	1564	87,7	104	6,6	1601	87,9	114	7,1	0,93		Algorithm converged.	0,71	1,22	-0,005		Algorithm converged.	-0,022	0,013	0,93		Algorithm converged.	0,72	1,21	0,6010	0,7002	1,07		Algorithm converged.	0,83	1,38
		>= 65	219	12,3	18	8,2	221	12,1	17	7,7	1,07		Algorithm converged.	0,54	2,14	0,005		Algorithm converged.	-0,045	0,056	1,07		Algorithm converged.	0,57	2,02	0,8382		0,94		Algorithm converged.	0,50	1,77
	CERUMEN IMPACTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONDUCTIVE DEAFNESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEAFNESS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEAFNESS BILATERAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEAFNESS UNILATERAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EAR CONGESTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EAR DISCOMFORT	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	EAR DISORDER	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EAR PAIN	< 65	1564	87,7	12	0,8	1601	87,9	14	0,9	0,88		Algorithm converged.	0,40	1,90	-0,001		Algorithm converged.	-0,007	0,005	0,88		Algorithm converged.	0,41	1,89	0,7385	-	1,14		Algorithm converged.	0,53	2,46
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTERNAL EAR INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOACUSIS	< 65	1564	87,7	3	0,2	1601	87,9	6	0,4	0,51		Algorithm converged.	0,13	2,05	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,13	2,04	0,3429	-	1,95		Algorithm converged.	0,49	7,80
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENIERE'S DISEASE	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MIDDLE EAR INFLAMMATION	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTOLITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTOTOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PRESBYACUSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINNITUS	< 65	1564	87,7	27	1,7	1601	87,9	27	1,7	1,02		Algorithm converged.	0,60	1,75	0,000		Algorithm converged.	-0,009	0,009	1,02		Algorithm converged.	0,60	1,74	0,9309	-	0,98		Algorithm converged.	0,58	1,66
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TYMPANIC MEMBRANE PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	< 65	1564	87,7	46	2,9	1601	87,9	55	3,4	0,85		Algorithm converged.	0,57	1,27	-0,005		Algorithm converged.	-0,017	0,007	0,86		Algorithm converged.	0,58	1,26	0,4296	0,4467	1,17		Algorithm converged.	0,79	1,72
		>= 65	219	12,3	11	5,0	221	12,1	9	4,1	1,25		Algorithm converged.	0,51	3,07	0,010		Algorithm converged.	-0,029	0,048	1,23		Algorithm converged.	0,52	2,92	0,6330		0,81		Algorithm converged.	0,34	1,92
	VERTIGO POSITIONAL	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	< 65	1564	87,7	15	1,0	1601	87,9	19	1,2	0,81		Algorithm converged.	0,41	1,59	-0,002		Algorithm converged.	-0,009	0,005	0,81		Algorithm converged.	0,41	1,58	0,5353	-	1,24		Algorithm converged.	0,63	2,43
		>= 65	219	12,3	2	0,9	221	12,1	5	2,3	0,40		Algorithm converged.	0,08	2,07	-0,013		Algorithm converged.	-0,037	0,010	0,40		Algorithm converged.	0,08	2,06	0,2751		2,48		Algorithm converged.	0,49	12,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AUTOIMMUNE THYROIDITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CUSHING'S SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CUSHINGOID	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GOITRE	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPARATHYROIDISM PRIMARY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPROLACTINAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOTHYROIDISM	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	STEROID WITHDRAWAL SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID CYST	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID MASS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	< 65	1564	87,7	391	25,0	1601	87,9	388	24,2	1,04		Algorithm converged.	0,89	1,23	0,008		Algorithm converged.	-0,022	0,038	1,03		Algorithm converged.	0,91	1,17	0,6173	0,8916	0,97		Algorithm converged.	0,86	1,10
		>= 65	219	12,3	64	29,2	221	12,1	64	29,0	1,01		Algorithm converged.	0,67	1,53	0,003		Algorithm converged.	-0,082	0,088	1,01		Algorithm converged.	0,75	1,35	0,9513		0,99		Algorithm converged.	0,74	1,33

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABNORMAL SENSATION IN EYE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AMAUROSIS FUGAX	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AMBLYOPIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASTHENOPIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTIGMATISM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLEPHARITIS	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLEPHARITIS ALLERGIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLEPHAROSPASM	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARACT	< 65	1564	87,7	1	<0.1	1601	87,9	10	0,6	0,10		Algorithm converged.	0,01	0,80	-0,006		Algorithm converged.	-0,010	-0,002	0,10		Algorithm converged.	0,01	0,80	0,0297	-	9,77		Algorithm converged.	1,25	76,22
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARACT CORTICAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CHALAZION	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVAL DEPOSIT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVAL HYPERAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVITIS ALLERGIC	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORNEAL EXFOLIATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DACRYOSTENOSIS ACQUIRED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DIPLOPIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY EYE	< 65	1564	87,7	83	5,3	1601	87,9	70	4,4	1,23		Algorithm converged.	0,88	1,70	0,009		Algorithm converged.	-0,006	0,024	1,21		Algorithm converged.	0,89	1,66	0,2211	0,6913	0,82		Algorithm converged.	0,60	1,12
		>= 65	219	12,3	10	4,6	221	12,1	10	4,5	1,01		Algorithm converged.	0,41	2,48	0,000		Algorithm converged.	-0,039	0,039	1,01		Algorithm converged.	0,43	2,38	0,9834		0,99		Algorithm converged.	0,42	2,33
	ECTROPION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA OF EYELID	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE ALLERGY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE DISCHARGE	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	EYE DISORDER	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	EYE INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE IRRITATION	< 65	1564	87,7	10	0,6	1601	87,9	7	0,4	1,47		Algorithm converged.	0,56	3,86	0,002		Algorithm converged.	-0,003	0,007	1,46		Algorithm converged.	0,56	3,83	0,4394	-	0,68		Algorithm converged.	0,26	1,79
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE MOVEMENT DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE OEDEMA	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE PAIN	< 65	1564	87,7	10	0,6	1601	87,9	11	0,7	0,93		Algorithm converged.	0,39	2,20	0,000		Algorithm converged.	-0,006	0,005	0,93		Algorithm converged.	0,40	2,18	0,8688	-	1,07		Algorithm converged.	0,46	2,52
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
	EYE PRURITUS	< 65	1564	87,7	8	0,5	1601	87,9	4	0,2	2,05		Algorithm converged.	0,62	6,83	0,003		Algorithm converged.	-0,002	0,007	2,05		Algorithm converged.	0,62	6,79	0,2412	-	0,49		Algorithm converged.	0,15	1,62
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	EYE SWELLING	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYELID FUNCTION DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID MARGIN CRUSTING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID OEDEMA	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID PTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID RASH	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID SKIN DRYNESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELIDS PRURITUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOREIGN BODY SENSATION IN EYES	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLAUCOMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATOCONUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LACRIMATION DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	< 65	1564	87,7	186	11,9	1601	87,9	212	13,2	0,88		Algorithm converged.	0,72	1,09	-0,013		Algorithm converged.	-0,037	0,010	0,90		Algorithm converged.	0,75	1,08	0,2528	0,1892	1,11		Algorithm converged.	0,93	1,34
		>= 65	219	12,3	42	19,2	221	12,1	35	15,8	1,26		Algorithm converged.	0,77	2,07	0,033		Algorithm converged.	-0,038	0,104	1,21		Algorithm converged.	0,81	1,82	0,3576		0,83		Algorithm converged.	0,55	1,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MACULAR OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MEIBOMIAN GLAND DYSFUNCTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	METAMORPHOPSIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOPIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NONINFECTIVE CONJUNCTIVITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	OCULAR DISCOMFORT	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR HYPERAEMIA	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OCULAR HYPERTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR TOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OPHTHALMOPLEGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPTIC NERVE DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORBITAL GRANULOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLOEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIORBITAL OEDEMA	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIORBITAL SWELLING	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHOTOPHOBIA	< 65	1564	87,7	5	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHOTOPSIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PTERYGIUM	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RETINAL VASCULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCLERAL DISORDER	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCLERAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULCERATIVE KERATITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UVEITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERNAL KERATOCONJUNCTIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VISION BLURRED	< 65	1564	87,7	37	2,4	1601	87,9	39	2,4	0,97		Algorithm converged.	0,62	1,53	-0,001		Algorithm converged.	-0,011	0,010	0,97		Algorithm converged.	0,62	1,51	0,8973	-	1,03		Algorithm converged.	0,66	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83
	VISUAL ACUITY REDUCED	< 65	1564	87,7	8	0,5	1601	87,9	5	0,3	1,64		Algorithm converged.	0,54	5,03	0,002		Algorithm converged.	-0,002	0,006	1,64		Algorithm converged.	0,54	5,00	0,3859	-	0,61		Algorithm converged.	0,20	1,86
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	VISUAL FIELD DEFECT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VISUAL IMPAIRMENT	< 65	1564	87,7	34	2,2	1601	87,9	16	1,0	2,20		Algorithm converged.	1,21	4,00	0,012		Algorithm converged.	0,003	0,020	2,18		Algorithm converged.	1,21	3,92	0,0098	-	0,46		Algorithm converged.	0,25	0,83
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS DETACHMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS FLOATERS	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS OPACITIES	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	XEROPHTHALMIA	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	1475	94,3	1601	87,9	1428	89,2	2,01		Algorithm converged.	1,54	2,62	0,051		Algorithm converged.	0,032	0,070	1,06		Algorithm converged.	1,04	1,08	<.0001	0,9500	0,95		Algorithm converged.	0,93	0,97
		>= 65	219	12,3	212	96,8	221	12,1	202	91,4	2,85		Algorithm converged.	1,17	6,92	0,054		Algorithm converged.	0,010	0,098	1,06		Algorithm converged.	1,01	1,11	0,0168		0,94		Algorithm converged.	0,90	0,99
	ABDOMINAL DISCOMFORT	< 65	1564	87,7	14	0,9	1601	87,9	21	1,3	0,68		Algorithm converged.	0,34	1,34	-0,004		Algorithm converged.	-0,011	0,003	0,68		Algorithm converged.	0,35	1,34	0,2656	0,9843	1,47		Algorithm converged.	0,75	2,87
		>= 65	219	12,3	4	1,8	221	12,1	6	2,7	0,67		Algorithm converged.	0,19	2,40	-0,009		Algorithm converged.	-0,037	0,019	0,67		Algorithm converged.	0,19	2,35	0,5347		1,49		Algorithm converged.	0,43	5,19
	ABDOMINAL DISTENSION	< 65	1564	87,7	52	3,3	1601	87,9	40	2,5	1,34		Algorithm converged.	0,88	2,04	0,008		Algorithm converged.	-0,003	0,020	1,33		Algorithm converged.	0,89	2,00	0,1680	-	0,75		Algorithm converged.	0,50	1,13
		>= 65	219	12,3	4	1,8	221	12,1	1	0,5	4,09		Algorithm converged.	0,45	36,92	0,014		Algorithm converged.	-0,006	0,034	4,04		Algorithm converged.	0,45	35,83	0,2103		0,25		Algorithm converged.	0,03	2,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL HERNIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL PAIN	< 65	1564	87,7	170	10,9	1601	87,9	160	10,0	1,10		Algorithm converged.	0,87	1,38	0,009		Algorithm converged.	-0,013	0,030	1,09		Algorithm converged.	0,89	1,33	0,4204	0,8765	0,92		Algorithm converged.	0,75	1,13
		>= 65	219	12,3	30	13,7	221	12,1	29	13,1	1,05		Algorithm converged.	0,61	1,82	0,006		Algorithm converged.	-0,058	0,069	1,04		Algorithm converged.	0,65	1,68	0,8592		0,96		Algorithm converged.	0,60	1,54
	ABDOMINAL PAIN LOWER	< 65	1564	87,7	3	0,2	1601	87,9	7	0,4	0,44		Algorithm converged.	0,11	1,70	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2319	-	2,28		Algorithm converged.	0,59	8,80
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ABDOMINAL PAIN UPPER	< 65	1564	87,7	148	9,5	1601	87,9	141	8,8	1,08		Algorithm converged.	0,85	1,38	0,007		Algorithm converged.	-0,014	0,027	1,07		Algorithm converged.	0,86	1,34	0,5220	0,1023	0,93		Algorithm converged.	0,75	1,16
		>= 65	219	12,3	27	12,3	221	12,1	15	6,8	1,93		Algorithm converged.	1,00	3,74	0,055		Algorithm converged.	0,001	0,110	1,82		Algorithm converged.	0,99	3,32	0,0523		0,55		Algorithm converged.	0,30	1,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL RIGIDITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABNORMAL FAECES	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACID PEPTIC DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE				NE	NE	NE		NE			NE	NE
	AEROPHAGIA	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAESTHESIA ORAL	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL ERYTHEMA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FISSURE	< 65	1564	87,7	14	0,9	1601	87,9	11	0,7	1,31		Algorithm converged.	0,59	2,88	0,002		Algorithm converged.	-0,004	0,008	1,30		Algorithm converged.	0,59	2,86	0,5098	-	0,77		Algorithm converged.	0,35	1,69
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ANAL FISTULA	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1	5,13		Algorithm converged.	0,60	43,97	0,003		Algorithm converged.	0,000	0,006	5,12		Algorithm converged.	0,60	43,76	0,1359	-	0,20		Algorithm converged.	0,02	1,67
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL HAEMORRHAGE	< 65	1564	87,7	7	0,4	1601	87,9	12	0,7	0,60		Algorithm converged.	0,23	1,52	-0,003		Algorithm converged.	-0,008	0,002	0,60		Algorithm converged.	0,24	1,51	0,2770	-	1,67		Algorithm converged.	0,66	4,24
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ANAL INCONTINENCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL INFLAMMATION	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	ANAL PRURITUS	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL SKIN TAGS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ANGULAR CHEILITIS	< 65	1564	87,7	16	1,0	1601	87,9	12	0,7	1,37		Algorithm converged.	0,65	2,90	0,003		Algorithm converged.	-0,004	0,009	1,36		Algorithm converged.	0,65	2,88	0,4133	-	0,73		Algorithm converged.	0,35	1,54
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	ANORECTAL DISCOMFORT	< 65	1564	87,7	6	0,4	1601	87,9	3	0,2	2,05		Algorithm converged.	0,51	8,22	0,002		Algorithm converged.	-0,002	0,006	2,05		Algorithm converged.	0,51	8,17	0,3103	-	0,49		Algorithm converged.	0,12	1,95
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANORECTAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	< 65	1564	87,7	24	1,5	1601	87,9	18	1,1	1,37		Algorithm converged.	0,74	2,54	0,004		Algorithm converged.	-0,004	0,012	1,36		Algorithm converged.	0,74	2,50	0,3153	-	0,73		Algorithm converged.	0,40	1,34
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APTYALISM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASCITES	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREATH ODOUR	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHANGE OF BOWEL HABIT	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHAPPED LIPS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEILITIS	< 65	1564	87,7	4	0,3	1601	87,9	6	0,4	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,005	0,003	0,68		Algorithm converged.	0,19	2,41	0,5533	-	1,47		Algorithm converged.	0,41	5,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC GASTRITIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	COLITIS	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS ISCHAEMIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	< 65	1564	87,7	439	28,1	1601	87,9	480	30,0	0,91		Algorithm converged.	0,78	1,06	-0,019		Algorithm converged.	-0,051	0,012	0,94		Algorithm converged.	0,84	1,04	0,2363	0,6955	1,07		Algorithm converged.	0,96	1,19
		>= 65	219	12,3	67	30,6	221	12,1	68	30,8	0,99		Algorithm converged.	0,66	1,49	-0,002		Algorithm converged.	-0,088	0,084	0,99		Algorithm converged.	0,75	1,32	0,9681		1,01		Algorithm converged.	0,76	1,33
	DENTAL CARIES	< 65	1564	87,7	9	0,6	1601	87,9	9	0,6	1,02		Algorithm converged.	0,41	2,59	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,41	2,57	0,9603	-	0,98		Algorithm converged.	0,39	2,45
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	DIARRHOEA	< 65	1564	87,7	1085	69,4	1601	87,9	707	44,2	2,86		Algorithm converged.	2,48	3,31	0,252		Algorithm converged.	0,219	0,286	1,57		Algorithm converged.	1,47	1,68	<.0001	0,3942	0,64		Algorithm converged.	0,60	0,68
		>= 65	219	12,3	170	77,6	221	12,1	117	52,9	3,08		Algorithm converged.	2,04	4,66	0,247		Algorithm converged.	0,161	0,333	1,47		Algorithm converged.	1,27	1,69	<.0001		0,68		Algorithm converged.	0,59	0,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA HAEMORRHAGIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULUM INTESTINAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULUM OESOPHAGEAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY MOUTH	< 65	1564	87,7	90	5,8	1601	87,9	89	5,6	1,04		Algorithm converged.	0,77	1,40	0,002		Algorithm converged.	-0,014	0,018	1,04		Algorithm converged.	0,78	1,38	0,8119	0,5261	0,97		Algorithm converged.	0,73	1,28
		>= 65	219	12,3	17	7,8	221	12,1	13	5,9	1,35		Algorithm converged.	0,64	2,84	0,019		Algorithm converged.	-0,028	0,066	1,32		Algorithm converged.	0,66	2,65	0,4358		0,76		Algorithm converged.	0,38	1,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSCHEZIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPEPSIA	< 65	1564	87,7	214	13,7	1601	87,9	222	13,9	0,98		Algorithm converged.	0,80	1,21	-0,002		Algorithm converged.	-0,026	0,022	0,99		Algorithm converged.	0,83	1,17	0,8810	0,4384	1,01		Algorithm converged.	0,85	1,21
		>= 65	219	12,3	29	13,2	221	12,1	24	10,9	1,25		Algorithm converged.	0,70	2,23	0,024		Algorithm converged.	-0,037	0,085	1,22		Algorithm converged.	0,73	2,03	0,4437		0,82		Algorithm converged.	0,49	1,36
	DYSPHAGIA	< 65	1564	87,7	50	3,2	1601	87,9	39	2,4	1,32		Algorithm converged.	0,87	2,02	0,008		Algorithm converged.	-0,004	0,019	1,31		Algorithm converged.	0,87	1,98	0,1969	0,8992	0,76		Algorithm converged.	0,50	1,15
		>= 65	219	12,3	6	2,7	221	12,1	5	2,3	1,22		Algorithm converged.	0,37	4,05	0,005		Algorithm converged.	-0,024	0,034	1,21		Algorithm converged.	0,38	3,91	0,7489		0,83		Algorithm converged.	0,26	2,67
	ENTERITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ENTEROCOLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPIGASTRIC DISCOMFORT	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERUCTATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FAECALOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAECES SOFT	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLATULENCE	< 65	1564	87,7	31	2,0	1601	87,9	28	1,7	1,14		Algorithm converged.	0,68	1,90	0,002		Algorithm converged.	-0,007	0,012	1,13		Algorithm converged.	0,68	1,88	0,6280	-	0,88		Algorithm converged.	0,53	1,46
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOOD POISONING	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FREQUENT BOWEL MOVEMENTS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNCTIONAL GASTROINTESTINAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC DILATATION	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC MUCOSA ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC POLYPS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	GASTRIC ULCER	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	< 65	1564	87,7	37	2,4	1601	87,9	27	1,7	1,41		Algorithm converged.	0,86	2,33	0,007		Algorithm converged.	-0,003	0,017	1,40		Algorithm converged.	0,86	2,29	0,1768	0,7285	0,71		Algorithm converged.	0,44	1,16
		>= 65	219	12,3	7	3,2	221	12,1	4	1,8	1,79		Algorithm converged.	0,52	6,21	0,014		Algorithm converged.	-0,015	0,043	1,77		Algorithm converged.	0,52	5,95	0,3586		0,57		Algorithm converged.	0,17	1,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRITIS EROSIVE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL DISORDER	< 65	1564	87,7	12	0,8	1601	87,9	14	0,9	0,88		Algorithm converged.	0,40	1,90	-0,001		Algorithm converged.	-0,007	0,005	0,88		Algorithm converged.	0,41	1,89	0,7385	-	1,14		Algorithm converged.	0,53	2,46
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL INFLAMMATION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL MOTILITY DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL MUCOSAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PAIN	< 65	1564	87,7	18	1,2	1601	87,9	9	0,6	2,06		Algorithm converged.	0,92	4,60	0,006		Algorithm converged.	-0,001	0,012	2,05		Algorithm converged.	0,92	4,54	0,0781	-	0,49		Algorithm converged.	0,22	1,08
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL SOUNDS ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	GASTROOESOPHAGEAL REFLUX DISEASE	< 65	1564	87,7	83	5,3	1601	87,9	73	4,6	1,17		Algorithm converged.	0,85	1,62	0,007		Algorithm converged.	-0,008	0,023	1,16		Algorithm converged.	0,86	1,58	0,3321	0,4457	0,86		Algorithm converged.	0,63	1,17
		>= 65	219	12,3	7	3,2	221	12,1	9	4,1	0,78		Algorithm converged.	0,28	2,13	-0,009		Algorithm converged.	-0,044	0,026	0,78		Algorithm converged.	0,30	2,07	0,6245		1,27		Algorithm converged.	0,48	3,36
	GINGIVAL ATROPHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL BLEEDING	< 65	1564	87,7	14	0,9	1601	87,9	8	0,5	1,80		Algorithm converged.	0,75	4,30	0,004		Algorithm converged.	-0,002	0,010	1,79		Algorithm converged.	0,75	4,26	0,1869	-	0,56		Algorithm converged.	0,23	1,33
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18
	GINGIVAL PAIN	< 65	1564	87,7	12	0,8	1601	87,9	16	1,0	0,77		Algorithm converged.	0,36	1,62	-0,002		Algorithm converged.	-0,009	0,004	0,77		Algorithm converged.	0,36	1,62	0,4870	-	1,30		Algorithm converged.	0,62	2,74
		>= 65	219	12,3	4	1,8	221	12,1	1	0,5	4,09		Algorithm converged.	0,45	36,92	0,014		Algorithm converged.	-0,006	0,034	4,04		Algorithm converged.	0,45	35,83	0,2103		0,25		Algorithm converged.	0,03	2,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GINGIVAL SWELLING	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVAL ULCERATION	< 65	1564	87,7	2	0,1	1601	87,9	9	0,6	0,23		Algorithm converged.	0,05	1,05	-0,004		Algorithm converged.	-0,008	0,000	0,23		Algorithm converged.	0,05	1,05	0,0580	-	4,40		Algorithm converged.	0,95	20,31
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLOSSITIS	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	GLOSSODYNIA	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOCHEZIA	< 65	1564	87,7	9	0,6	1601	87,9	10	0,6	0,92		Algorithm converged.	0,37	2,27	0,000		Algorithm converged.	-0,006	0,005	0,92		Algorithm converged.	0,38	2,26	0,8580	-	1,09		Algorithm converged.	0,44	2,66
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	< 65	1564	87,7	16	1,0	1601	87,9	14	0,9	1,17		Algorithm converged.	0,57	2,41	0,001		Algorithm converged.	-0,005	0,008	1,17		Algorithm converged.	0,57	2,39	0,6666	-	0,85		Algorithm converged.	0,42	1,75
		>= 65	219	12,3	7	3,2	221	12,1	2	0,9	3,62		Algorithm converged.	0,74	17,60	0,023		Algorithm converged.	-0,004	0,049	3,53		Algorithm converged.	0,74	16,81	0,1130		0,28		Algorithm converged.	0,06	1,35
	HAEMORRHOIDS	< 65	1564	87,7	122	7,8	1601	87,9	85	5,3	1,51		Algorithm converged.	1,13	2,01	0,025		Algorithm converged.	0,008	0,042	1,47		Algorithm converged.	1,12	1,92	0,0049	0,5022	0,68		Algorithm converged.	0,52	0,89
		>= 65	219	12,3	12	5,5	221	12,1	11	5,0	1,11		Algorithm converged.	0,48	2,56	0,005		Algorithm converged.	-0,037	0,047	1,10		Algorithm converged.	0,50	2,44	0,8131		0,91		Algorithm converged.	0,41	2,01
	HIATUS HERNIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERAESTHESIA TEETH	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERCHLORHYDRIA	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOAESTHESIA ORAL	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ILEUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	IMPAIRED GASTRIC EMPTYING	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRRITABLE BOWEL SYNDROME	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LARGE INTESTINAL ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARGE INTESTINE POLYP	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP DRY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP EROSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LIP OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LIP PAIN	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LIP SWELLING	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LIP ULCERATION	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOOSE TOOTH	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MELAENA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MOUTH HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MOUTH ULCERATION	< 65	1564	87,7	46	2,9	1601	87,9	49	3,1	0,96		Algorithm converged.	0,64	1,44	-0,001		Algorithm converged.	-0,013	0,011	0,96		Algorithm converged.	0,65	1,43	0,8440	0,5547	1,04		Algorithm converged.	0,70	1,55
		>= 65	219	12,3	7	3,2	221	12,1	10	4,5	0,70		Algorithm converged.	0,26	1,86	-0,013		Algorithm converged.	-0,049	0,023	0,71		Algorithm converged.	0,27	1,82	0,4722		1,42		Algorithm converged.	0,55	3,65
	NAUSEA	< 65	1564	87,7	1076	68,8	1601	87,9	1069	66,8	1,10		Algorithm converged.	0,95	1,27	0,020		Algorithm converged.	-0,012	0,053	1,03		Algorithm converged.	0,98	1,08	0,2224	0,0007	0,97		Algorithm converged.	0,93	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	157	71,7	221	12,1	118	53,4	2,21		Algorithm converged.	1,49	3,28	0,183		Algorithm converged.	0,094	0,272	1,34		Algorithm converged.	1,16	1,56	0,0001		0,74		Algorithm converged.	0,64	0,86
	NONINFECTIVE GINGIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ODYNOPHAGIA	< 65	1564	87,7	12	0,8	1601	87,9	10	0,6	1,23		Algorithm converged.	0,53	2,86	0,001		Algorithm converged.	-0,004	0,007	1,23		Algorithm converged.	0,53	2,83	0,6297	-	0,81		Algorithm converged.	0,35	1,88
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA MOUTH	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL DISCOMFORT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL PAIN	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OESOPHAGEAL SPASM	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL STENOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGITIS	< 65	1564	87,7	17	1,1	1601	87,9	17	1,1	1,02		Algorithm converged.	0,52	2,01	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,52	2,00	0,9454	-	0,98		Algorithm converged.	0,50	1,91
		>= 65	219	12,3	7	3,2	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL DISCOMFORT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL DYSAESTHESIA	< 65	1564	87,7	2	0,1	1601	87,9	9	0,6	0,23		Algorithm converged.	0,05	1,05	-0,004		Algorithm converged.	-0,008	0,000	0,23		Algorithm converged.	0,05	1,05	0,0580	-	4,40		Algorithm converged.	0,95	20,31
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL LICHEN PLANUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL MUCOSA HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ORAL MUCOSAL BLISTERING	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL MUCOSAL ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL MUCOSAL ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL PAIN	< 65	1564	87,7	17	1,1	1601	87,9	31	1,9	0,56		Algorithm converged.	0,31	1,01	-0,008		Algorithm converged.	-0,017	0,000	0,56		Algorithm converged.	0,31	1,01	0,0540	0,0066	1,78		Algorithm converged.	0,99	3,21
		>= 65	219	12,3	10	4,6	221	12,1	3	1,4	3,48		Algorithm converged.	0,94	12,81	0,032		Algorithm converged.	0,001	0,064	3,36		Algorithm converged.	0,94	12,06	0,0625		0,30		Algorithm converged.	0,08	1,07
	OVERFLOW DIARRHOEA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	PANCREATIC DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PANCREATITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	PARAESTHESIA ORAL	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAROTID GLAND ENLARGEMENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PEPTIC ULCER	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTAL DISEASE	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCTALGIA	< 65	1564	87,7	11	0,7	1601	87,9	6	0,4	1,88		Algorithm converged.	0,69	5,10	0,003		Algorithm converged.	-0,002	0,008	1,88		Algorithm converged.	0,70	5,06	0,2137	-	0,53		Algorithm converged.	0,20	1,44
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCTITIS	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	< 65	1564	87,7	23	1,5	1601	87,9	14	0,9	1,69		Algorithm converged.	0,87	3,30	0,006		Algorithm converged.	-0,002	0,013	1,68		Algorithm converged.	0,87	3,26	0,1231	-	0,59		Algorithm converged.	0,31	1,15
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36
	RECTAL TENESMUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	REFLUX GASTRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RETCHING	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL			Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	SALIVARY GLAND PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALIVARY HYPERSECRETION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	SMALL INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	< 65	1564	87,7	450	28,8	1601	87,9	380	23,7	1,30		Algorithm converged.	1,11	1,52	0,050		Algorithm converged.	0,020	0,081	1,21		Algorithm converged.	1,08	1,36	0,0013	0,6470	0,82		Algorithm converged.	0,73	0,93
		>= 65	219	12,3	65	29,7	221	12,1	50	22,6	1,44		Algorithm converged.	0,94	2,22	0,071		Algorithm converged.	-0,011	0,152	1,31		Algorithm converged.	0,95	1,80	0,0941		0,76		Algorithm converged.	0,55	1,05

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRAWBERRY TONGUE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBILEUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SWOLLEN TONGUE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONGUE BLISTERING	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE COATED	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	TONGUE DISCOLOURATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONGUE DISCOMFORT	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONGUE PRURITUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE ULCERATION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH DISCOLOURATION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH IMPACTED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH LOSS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TOOTHACHE	< 65	1564	87,7	32	2,0	1601	87,9	40	2,5	0,82		Algorithm converged.	0,51	1,30	-0,005		Algorithm converged.	-0,015	0,006	0,82		Algorithm converged.	0,52	1,30	0,3943	-	1,22		Algorithm converged.	0,77	1,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	6	2,7	221	12,1	3	1,4	2,05		Algorithm converged.	0,51	8,29	0,014		Algorithm converged.	-0,013	0,040	2,02		Algorithm converged.	0,51	7,97	0,3162		0,50		Algorithm converged.	0,13	1,96
	UMBILICAL HERNIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VOMITING	< 65	1564	87,7	534	34,1	1601	87,9	518	32,4	1,08		Algorithm converged.	0,93	1,26	0,018		Algorithm converged.	-0,015	0,051	1,06		Algorithm converged.	0,96	1,16	0,2856	0,0371	0,95		Algorithm converged.	0,86	1,05
		>= 65	219	12,3	71	32,4	221	12,1	48	21,7	1,73		Algorithm converged.	1,13	2,65	0,107		Algorithm converged.	0,025	0,189	1,49		Algorithm converged.	1,09	2,05	0,0127		0,67		Algorithm converged.	0,49	0,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	1312	83,9	1601	87,9	1296	80,9	1,23		Algorithm converged.	1,02	1,47	0,029		Algorithm converged.	0,003	0,056	1,04		Algorithm converged.	1,00	1,07	0,0300	0,7083	0,96		Algorithm converged.	0,93	1,00
		>= 65	219	12,3	188	85,8	221	12,1	180	81,4	1,38		Algorithm converged.	0,83	2,30	0,044		Algorithm converged.	-0,025	0,113	1,05		Algorithm converged.	0,97	1,14	0,2132		0,95		Algorithm converged.	0,87	1,03
	ADVERSE DRUG REACTION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPLICATION SITE RASH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ASTHENIA	< 65	1564	87,7	318	20,3	1601	87,9	319	19,9	1,03		Algorithm converged.	0,86	1,22	0,004		Algorithm converged.	-0,024	0,032	1,02		Algorithm converged.	0,89	1,17	0,7750	0,1750	0,98		Algorithm converged.	0,85	1,13
		>= 65	219	12,3	62	28,3	221	12,1	48	21,7	1,42		Algorithm converged.	0,92	2,20	0,066		Algorithm converged.	-0,015	0,147	1,30		Algorithm converged.	0,94	1,81	0,1124		0,77		Algorithm converged.	0,55	1,06
	AXILLARY PAIN	< 65	1564	87,7	26	1,7	1601	87,9	18	1,1	1,49		Algorithm converged.	0,81	2,72	0,005		Algorithm converged.	-0,003	0,014	1,48		Algorithm converged.	0,81	2,69	0,1991	-	0,68		Algorithm converged.	0,37	1,23
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE BRUISE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE ERYTHEMA	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE INFLAMMATION	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE IRRITATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE PAIN	< 65	1564	87,7	13	0,8	1601	87,9	16	1,0	0,83		Algorithm converged.	0,40	1,73	-0,002		Algorithm converged.	-0,008	0,005	0,83		Algorithm converged.	0,40	1,72	0,6201	-	1,20		Algorithm converged.	0,58	2,49
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE PRURITUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE RASH	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST DISCOMFORT	< 65	1564	87,7	26	1,7	1601	87,9	31	1,9	0,86		Algorithm converged.	0,51	1,45	-0,003		Algorithm converged.	-0,012	0,007	0,86		Algorithm converged.	0,51	1,44	0,5628	-	1,16		Algorithm converged.	0,69	1,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHEST PAIN	< 65	1564	87,7	40	2,6	1601	87,9	53	3,3	0,77		Algorithm converged.	0,51	1,16	-0,008		Algorithm converged.	-0,019	0,004	0,77		Algorithm converged.	0,52	1,16	0,2113	0,0107	1,29		Algorithm converged.	0,86	1,94
		>= 65	219	12,3	11	5,0	221	12,1	3	1,4	3,84		Algorithm converged.	1,06	13,97	0,037		Algorithm converged.	0,004	0,069	3,70		Algorithm converged.	1,05	13,08	0,0423		0,27		Algorithm converged.	0,08	0,96
	CHILLS	< 65	1564	87,7	56	3,6	1601	87,9	69	4,3	0,82		Algorithm converged.	0,58	1,18	-0,007		Algorithm converged.	-0,021	0,006	0,83		Algorithm converged.	0,59	1,17	0,2931	0,0998	1,20		Algorithm converged.	0,85	1,70
		>= 65	219	12,3	14	6,4	221	12,1	8	3,6	1,82		Algorithm converged.	0,75	4,43	0,028		Algorithm converged.	-0,013	0,068	1,77		Algorithm converged.	0,76	4,12	0,1889		0,57		Algorithm converged.	0,24	1,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COMPLICATION ASSOCIATED WITH DEVICE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CREPITATIONS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CRYING	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYST	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYST RUPTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED THROMBOSIS	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	DISCOMFORT	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPLASIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENANTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXERCISE TOLERANCE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FACE OEDEMA	< 65	1564	87,7	20	1,3	1601	87,9	31	1,9	0,66		Algorithm converged.	0,37	1,16	-0,007		Algorithm converged.	-0,015	0,002	0,66		Algorithm converged.	0,38	1,15	0,1449	-	1,51		Algorithm converged.	0,87	2,64
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
	FACIAL PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAT NECROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	< 65	1564	87,7	758	48,5	1601	87,9	702	43,8	1,20		Algorithm converged.	1,05	1,39	0,046		Algorithm converged.	0,011	0,081	1,11		Algorithm converged.	1,03	1,19	0,0092	0,6158	0,90		Algorithm converged.	0,84	0,98
		>= 65	219	12,3	108	49,3	221	12,1	104	47,1	1,09		Algorithm converged.	0,75	1,59	0,023		Algorithm converged.	-0,071	0,116	1,05		Algorithm converged.	0,86	1,27	0,6359		0,95		Algorithm converged.	0,79	1,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEELING ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEELING COLD	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	FEELING HOT	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	FEELING JITTERY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEELING OF BODY TEMPERATURE CHANGE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FOREIGN BODY REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAIT DISTURBANCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91
	GENERALISED OEDEMA	< 65	1564	87,7	7	0,4	1601	87,9	10	0,6	0,72		Algorithm converged.	0,27	1,88	-0,002		Algorithm converged.	-0,007	0,003	0,72		Algorithm converged.	0,27	1,88	0,4977	-	1,40		Algorithm converged.	0,53	3,66
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HUNGER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPYREXIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHERMIA	< 65	1564	87,7	6	0,4	1601	87,9	11	0,7	0,56		Algorithm converged.	0,21	1,51	-0,003		Algorithm converged.	-0,008	0,002	0,56		Algorithm converged.	0,21	1,51	0,2497	-	1,79		Algorithm converged.	0,66	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOTHERMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ILL-DEFINED DISORDER	< 65	1564	87,7	12	0,8	1601	87,9	15	0,9	0,82		Algorithm converged.	0,38	1,75	-0,002		Algorithm converged.	-0,008	0,005	0,82		Algorithm converged.	0,38	1,74	0,6045	-	1,22		Algorithm converged.	0,57	2,60
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	ILLNESS	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	IMPAIRED HEALING	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IMPLANT SITE INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INDURATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLAMMATION	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA LIKE ILLNESS	< 65	1564	87,7	95	6,1	1601	87,9	83	5,2	1,18		Algorithm converged.	0,87	1,60	0,009		Algorithm converged.	-0,007	0,025	1,17		Algorithm converged.	0,88	1,56	0,2778	0,2788	0,85		Algorithm converged.	0,64	1,14
		>= 65	219	12,3	5	2,3	221	12,1	8	3,6	0,62		Algorithm converged.	0,20	1,93	-0,013		Algorithm converged.	-0,045	0,018	0,63		Algorithm converged.	0,21	1,90	0,4122		1,59		Algorithm converged.	0,53	4,77
	INFUSION SITE EXTRAVASATION	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE BRUISING	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE DISCOMFORT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE EXTRAVASATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE HYPERSENSITIVITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE PAIN	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE PHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE PRURITUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE RASH	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE REACTION	< 65	1564	87,7	9	0,6	1601	87,9	6	0,4	1,54		Algorithm converged.	0,55	4,33	0,002		Algorithm converged.	-0,003	0,007	1,54		Algorithm converged.	0,55	4,30	0,4148	-	0,65		Algorithm converged.	0,23	1,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INJECTION SITE THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOCALISED OEDEMA	< 65	1564	87,7	14	0,9	1601	87,9	11	0,7	1,31		Algorithm converged.	0,59	2,88	0,002		Algorithm converged.	-0,004	0,008	1,30		Algorithm converged.	0,59	2,86	0,5098	-	0,77		Algorithm converged.	0,35	1,69
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	MALAISE	< 65	1564	87,7	41	2,6	1601	87,9	62	3,9	0,67		Algorithm converged.	0,45	1,00	-0,013		Algorithm converged.	-0,025	0,000	0,68		Algorithm converged.	0,46	1,00	0,0489	0,1424	1,48		Algorithm converged.	1,00	2,18
		>= 65	219	12,3	14	6,4	221	12,1	11	5,0	1,30		Algorithm converged.	0,58	2,94	0,014		Algorithm converged.	-0,029	0,057	1,28		Algorithm converged.	0,60	2,77	0,5226		0,78		Algorithm converged.	0,36	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MEDICAL DEVICE PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAPLASIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DRYNESS	< 65	1564	87,7	30	1,9	1601	87,9	21	1,3	1,47		Algorithm converged.	0,84	2,58	0,006		Algorithm converged.	-0,003	0,015	1,46		Algorithm converged.	0,84	2,54	0,1782	-	0,68		Algorithm converged.	0,39	1,19
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUCOSAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	< 65	1564	87,7	358	22,9	1601	87,9	269	16,8	1,47		Algorithm converged.	1,23	1,75	0,061		Algorithm converged.	0,033	0,089	1,36		Algorithm converged.	1,18	1,57	<.0001	0,1603	0,73		Algorithm converged.	0,64	0,85
		>= 65	219	12,3	47	21,5	221	12,1	46	20,8	1,04		Algorithm converged.	0,66	1,64	0,006		Algorithm converged.	-0,070	0,083	1,03		Algorithm converged.	0,72	1,48	0,8681		0,97		Algorithm converged.	0,68	1,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUCOSAL TOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL ULCERATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NODULE	< 65	1564	87,7	5	0,3	1601	87,9	2	0,1	2,56		Algorithm converged.	0,50	13,24	0,002		Algorithm converged.	-0,001	0,005	2,56		Algorithm converged.	0,50	13,17	0,2610	-	0,39		Algorithm converged.	0,08	2,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NON-CARDIAC CHEST PAIN	< 65	1564	87,7	7	0,4	1601	87,9	13	0,8	0,55		Algorithm converged.	0,22	1,38	-0,004		Algorithm converged.	-0,009	0,002	0,55		Algorithm converged.	0,22	1,38	0,2026	-	1,81		Algorithm converged.	0,73	4,54
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OEDEMA	< 65	1564	87,7	97	6,2	1601	87,9	102	6,4	0,97		Algorithm converged.	0,73	1,29	-0,002		Algorithm converged.	-0,019	0,015	0,97		Algorithm converged.	0,74	1,27	0,8448	0,9316	1,03		Algorithm converged.	0,78	1,34
		>= 65	219	12,3	14	6,4	221	12,1	15	6,8	0,94		Algorithm converged.	0,44	1,99	-0,004		Algorithm converged.	-0,050	0,042	0,94		Algorithm converged.	0,47	1,90	0,8675		1,06		Algorithm converged.	0,53	2,15
	OEDEMA PERIPHERAL	< 65	1564	87,7	258	16,5	1601	87,9	320	20,0	0,79		Algorithm converged.	0,66	0,95	-0,035		Algorithm converged.	-0,062	-0,008	0,83		Algorithm converged.	0,71	0,96	0,0113	0,4240	1,21		Algorithm converged.	1,04	1,41
		>= 65	219	12,3	46	21,0	221	12,1	48	21,7	0,96		Algorithm converged.	0,61	1,51	-0,007		Algorithm converged.	-0,084	0,069	0,97		Algorithm converged.	0,68	1,38	0,8549		1,03		Algorithm converged.	0,72	1,48
	PAIN	< 65	1564	87,7	111	7,1	1601	87,9	110	6,9	1,04		Algorithm converged.	0,79	1,36	0,002		Algorithm converged.	-0,015	0,020	1,03		Algorithm converged.	0,80	1,33	0,8026	0,0120	0,97		Algorithm converged.	0,75	1,25
		>= 65	219	12,3	15	6,8	221	12,1	4	1,8	3,99		Algorithm converged.	1,30	12,22	0,050		Algorithm converged.	0,013	0,088	3,78		Algorithm converged.	1,28	11,22	0,0164		0,26		Algorithm converged.	0,09	0,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL SWELLING	< 65	1564	87,7	31	2,0	1601	87,9	33	2,1	0,96		Algorithm converged.	0,59	1,58	-0,001		Algorithm converged.	-0,011	0,009	0,96		Algorithm converged.	0,59	1,56	0,8744	-	1,04		Algorithm converged.	0,64	1,69
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PUNCTURE SITE PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PYREXIA	< 65	1564	87,7	326	20,8	1601	87,9	303	18,9	1,13		Algorithm converged.	0,95	1,34	0,019		Algorithm converged.	-0,009	0,047	1,10		Algorithm converged.	0,96	1,27	0,1766	0,1116	0,91		Algorithm converged.	0,79	1,04
		>= 65	219	12,3	33	15,1	221	12,1	43	19,5	0,73		Algorithm converged.	0,45	1,21	-0,044		Algorithm converged.	-0,114	0,027	0,77		Algorithm converged.	0,51	1,17	0,2255		1,29		Algorithm converged.	0,85	1,95
	SCAR INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SECRETION DISCHARGE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SENSATION OF FOREIGN BODY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAPUBIC PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SWELLING	< 65	1564	87,7	8	0,5	1601	87,9	6	0,4	1,37		Algorithm converged.	0,47	3,95	0,001		Algorithm converged.	-0,003	0,006	1,36		Algorithm converged.	0,47	3,92	0,5638	-	0,73		Algorithm converged.	0,25	2,11
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	SWELLING FACE	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4	1,71		Algorithm converged.	0,62	4,72	0,003		Algorithm converged.	-0,002	0,008	1,71		Algorithm converged.	0,62	4,68	0,2998	-	0,59		Algorithm converged.	0,21	1,61
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TEMPERATURE INTOLERANCE	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TEMPERATURE REGULATION DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDERNESS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THIRST	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ULCER	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UNEVALUABLE EVENT	< 65	1564	87,7	10	0,6	1601	87,9	2	0,1	5,14		Algorithm converged.	1,13	23,52	0,005		Algorithm converged.	0,001	0,009	5,12		Algorithm converged.	1,12	23,32	0,0348	-	0,20		Algorithm converged.	0,04	0,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VASCULAR DEVICE OCCLUSION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESSEL PUNCTURE SITE BRUISE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	XEROSIS	< 65	1564	87,7	10	0,6	1601	87,9	4	0,2	2,57		Algorithm converged.	0,80	8,21	0,004		Algorithm converged.	-0,001	0,009	2,56		Algorithm converged.	0,80	8,14	0,1116	-	0,39		Algorithm converged.	0,12	1,24
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	50	3,2	1601	87,9	56	3,5	0,91		Algorithm converged.	0,62	1,34	-0,003		Algorithm converged.	-0,016	0,010	0,91		Algorithm converged.	0,63	1,33	0,6382	-	1,09		Algorithm converged.	0,75	1,59
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91
	BILIARY COLIC	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLANGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS ACUTE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS CHRONIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CHOLESTASIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG-INDUCED LIVER INJURY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GALLBLADDER POLYP	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC CYST	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FUNCTION ABNORMAL	< 65	1564	87,7	13	0,8	1601	87,9	21	1,3	0,63		Algorithm converged.	0,31	1,26	-0,005		Algorithm converged.	-0,012	0,002	0,63		Algorithm converged.	0,32	1,26	0,1938	-	1,58		Algorithm converged.	0,79	3,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC STEATOSIS	< 65	1564	87,7	9	0,6	1601	87,9	10	0,6	0,92		Algorithm converged.	0,37	2,27	0,000		Algorithm converged.	-0,006	0,005	0,92		Algorithm converged.	0,38	2,26	0,8580	-	1,09		Algorithm converged.	0,44	2,66
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	HEPATITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HEPATITIS ACUTE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATOBILIARY DISEASE	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1	5,13		Algorithm converged.	0,60	43,97	0,003		Algorithm converged.	0,000	0,006	5,12		Algorithm converged.	0,60	43,76	0,1359	-	0,20		Algorithm converged.	0,02	1,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HEPATOTOXICITY	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERBILIRUBINAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRANSAMINASAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER INJURY	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR ICTERUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	89	5,7	1601	87,9	72	4,5	1,28		Algorithm converged.	0,93	1,76	0,012		Algorithm converged.	-0,003	0,027	1,27		Algorithm converged.	0,93	1,71	0,1276	0,9949	0,79		Algorithm converged.	0,58	1,07
		>= 65	219	12,3	10	4,6	221	12,1	8	3,6	1,27		Algorithm converged.	0,49	3,29	0,009		Algorithm converged.	-0,028	0,046	1,26		Algorithm converged.	0,51	3,14	0,6172		0,79		Algorithm converged.	0,32	1,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALLERGIC OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLERGY TO ANIMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC REACTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DECREASED IMMUNE RESPONSIVENESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	21	1,3	1601	87,9	11	0,7	1,97		Algorithm converged.	0,95	4,09	0,007		Algorithm converged.	0,000	0,014	1,95		Algorithm converged.	0,95	4,04	0,0705	-	0,51		Algorithm converged.	0,25	1,06
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FOOD ALLERGY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	< 65	1564	87,7	47	3,0	1601	87,9	47	2,9	1,02		Algorithm converged.	0,68	1,54	0,001		Algorithm converged.	-0,011	0,013	1,02		Algorithm converged.	0,69	1,52	0,9084	0,7898	0,98		Algorithm converged.	0,66	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	6	2,7	221	12,1	5	2,3	1,22		Algorithm converged.	0,37	4,05	0,005		Algorithm converged.	-0,024	0,034	1,21		Algorithm converged.	0,38	3,91	0,7489		0,83		Algorithm converged.	0,26	2,67
	IMMUNE SYSTEM DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED HYPERSENSITIVITY REACTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEASONAL ALLERGY	< 65	1564	87,7	14	0,9	1601	87,9	6	0,4	2,40		Algorithm converged.	0,92	6,26	0,005		Algorithm converged.	0,000	0,011	2,39		Algorithm converged.	0,92	6,20	0,0736	-	0,42		Algorithm converged.	0,16	1,09
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERUM SICKNESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	953	60,9	1601	87,9	925	57,8	1,14		Algorithm converged.	0,99	1,31	0,032		Algorithm converged.	-0,003	0,066	1,05		Algorithm converged.	1,00	1,12	0,0707	0,5993	0,95		Algorithm converged.	0,90	1,00
		>= 65	219	12,3	131	59,8	221	12,1	131	59,3	1,02		Algorithm converged.	0,70	1,50	0,005		Algorithm converged.	-0,086	0,097	1,01		Algorithm converged.	0,87	1,18	0,9079		0,99		Algorithm converged.	0,85	1,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ABSCESS JAW	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABSCESS LIMB	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS ORAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACARODERMATITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACTINOMYCOSIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE HEPATITIS B	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE SINUSITIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADENOVIRAL CONJUNCTIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ABSCESS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FUNGAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					
	APPENDICITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	APPENDICITIS PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ARTHRITIS INFECTIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASCARIASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERIAL VAGINOSIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL VULVOVAGINITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BARTHOLINITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BETA HAEMOLYTIC STREPTOCOCCAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BODY TINEA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BOTRYOMYCOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST CELLULITIS	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIOLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	< 65	1564	87,7	48	3,1	1601	87,9	65	4,1	0,75		Algorithm converged.	0,51	1,09	-0,010		Algorithm converged.	-0,023	0,003	0,76		Algorithm converged.	0,52	1,09	0,1345	0,4265	1,32		Algorithm converged.	0,92	1,91
		>= 65	219	12,3	9	4,1	221	12,1	8	3,6	1,14		Algorithm converged.	0,43	3,01	0,005		Algorithm converged.	-0,031	0,041	1,14		Algorithm converged.	0,45	2,89	0,7900		0,88		Algorithm converged.	0,35	2,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHITIS VIRAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BULLOUS IMPETIGO	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BURN INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CAMPYLOBACTER INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CANDIDA INFECTION	< 65	1564	87,7	23	1,5	1601	87,9	16	1,0	1,48		Algorithm converged.	0,78	2,81	0,005		Algorithm converged.	-0,003	0,012	1,47		Algorithm converged.	0,78	2,77	0,2326	-	0,68		Algorithm converged.	0,36	1,28
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARBUNCLE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	6	0,4	0,51		Algorithm converged.	0,13	2,05	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,13	2,04	0,3429	-	1,95		Algorithm converged.	0,49	7,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE				NE	NE	NE		NE			NE	NE
	CATHETER SITE PUSTULE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE				NE	NE	NE		NE			NE	NE
	CELLULITIS	< 65	1564	87,7	30	1,9	1601	87,9	28	1,7	1,10		Algorithm converged.	0,65	1,85	0,002		Algorithm converged.	-0,008	0,011	1,10		Algorithm converged.	0,66	1,83	0,7227	-	0,91		Algorithm converged.	0,55	1,52
		>= 65	219	12,3	4	1,8	221	12,1	5	2,3	0,80		Algorithm converged.	0,21	3,03	-0,004		Algorithm converged.	-0,031	0,022	0,81		Algorithm converged.	0,22	2,97	0,7472		1,24		Algorithm converged.	0,34	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CELLULITIS ORBITAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEST WALL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC SINUSITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC TONSILLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	CLOSTRIDIAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	CLOSTRIDIUM COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE COLITIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONJUNCTIVITIS	< 65	1564	87,7	100	6,4	1601	87,9	76	4,7	1,37		Algorithm converged.	1,01	1,86	0,016		Algorithm converged.	0,000	0,032	1,35		Algorithm converged.	1,01	1,80	0,0441	0,0436	0,74		Algorithm converged.	0,56	0,99
		>= 65	219	12,3	10	4,6	221	12,1	17	7,7	0,57		Algorithm converged.	0,26	1,28	-0,031		Algorithm converged.	-0,076	0,013	0,59		Algorithm converged.	0,28	1,27	0,1777		1,68		Algorithm converged.	0,79	3,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVITIS VIRAL	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS	< 65	1564	87,7	52	3,3	1601	87,9	36	2,2	1,50		Algorithm converged.	0,97	2,30	0,011		Algorithm converged.	-0,001	0,022	1,48		Algorithm converged.	0,97	2,25	0,0675	0,3069	0,68		Algorithm converged.	0,44	1,03
		>= 65	219	12,3	11	5,0	221	12,1	12	5,4	0,92		Algorithm converged.	0,40	2,13	-0,004		Algorithm converged.	-0,046	0,038	0,93		Algorithm converged.	0,42	2,05	0,8479		1,08		Algorithm converged.	0,49	2,40
	DENGUE FEVER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS INFECTED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATOPHYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	7	0,4	0,73		Algorithm converged.	0,23	2,31	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5922	-	1,37		Algorithm converged.	0,43	4,30
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	DEVICE RELATED SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIENTAMOEBA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISSEMINATED TUBERCULOSIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18
	DIVERTICULITIS INTESTINAL PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EAR INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	12	0,7	0,42		Algorithm converged.	0,15	1,21	-0,004		Algorithm converged.	-0,009	0,001	0,43		Algorithm converged.	0,15	1,21	0,1086	-	2,34		Algorithm converged.	0,83	6,64
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOCARDITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTERITIS INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ENTEROBIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS INFECTIOUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	< 65	1564	87,7	9	0,6	1601	87,9	5	0,3	1,85		Algorithm converged.	0,62	5,52	0,003		Algorithm converged.	-0,002	0,007	1,84		Algorithm converged.	0,62	5,49	0,2722	-	0,54		Algorithm converged.	0,18	1,62
		>= 65	219	12,3	7	3,2	221	12,1	1	0,5	7,26		Algorithm converged.	0,89	59,54	0,027		Algorithm converged.	0,003	0,052	7,06		Algorithm converged.	0,88	56,94	0,0663		0,14		Algorithm converged.	0,02	1,14
	ESCHERICHIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHERICHIA URINARY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE INFECTION	< 65	1564	87,7	9	0,6	1601	87,9	15	0,9	0,61		Algorithm converged.	0,27	1,40	-0,004		Algorithm converged.	-0,010	0,002	0,61		Algorithm converged.	0,27	1,40	0,2460	-	1,63		Algorithm converged.	0,71	3,71
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID FOLLICULITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOLLICULITIS	< 65	1564	87,7	25	1,6	1601	87,9	13	0,8	1,98		Algorithm converged.	1,01	3,89	0,008		Algorithm converged.	0,000	0,015	1,97		Algorithm converged.	1,01	3,83	0,0464	-	0,51		Algorithm converged.	0,26	0,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	FUNGAL INFECTION	< 65	1564	87,7	11	0,7	1601	87,9	8	0,5	1,41		Algorithm converged.	0,57	3,52	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,49	0,4606	-	0,71		Algorithm converged.	0,29	1,76
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	FUNGAL OESOPHAGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FUNGAL PHARYNGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNGAL SKIN INFECTION	< 65	1564	87,7	11	0,7	1601	87,9	7	0,4	1,61		Algorithm converged.	0,62	4,17	0,003		Algorithm converged.	-0,003	0,008	1,61		Algorithm converged.	0,63	4,14	0,3242	-	0,62		Algorithm converged.	0,24	1,60
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FURUNCLE	< 65	1564	87,7	4	0,3	1601	87,9	11	0,7	0,37		Algorithm converged.	0,12	1,17	-0,004		Algorithm converged.	-0,009	0,000	0,37		Algorithm converged.	0,12	1,17	0,0899	-	2,69		Algorithm converged.	0,86	8,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	< 65	1564	87,7	31	2,0	1601	87,9	31	1,9	1,02		Algorithm converged.	0,62	1,69	0,000		Algorithm converged.	-0,009	0,010	1,02		Algorithm converged.	0,63	1,68	0,9259	-	0,98		Algorithm converged.	0,60	1,60
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	GASTROENTERITIS VIRAL	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL FUNGAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL VIRAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL HERPES	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL HERPES SIMPLEX	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL INFECTION FEMALE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL INFECTION FUNGAL	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITOURINARY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GINGIVAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GINGIVITIS	< 65	1564	87,7	24	1,5	1601	87,9	26	1,6	0,94		Algorithm converged.	0,54	1,65	-0,001		Algorithm converged.	-0,010	0,008	0,94		Algorithm converged.	0,54	1,64	0,8401	-	1,06		Algorithm converged.	0,61	1,84
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GROIN ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	H1N1 INFLUENZA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HELICOBACTER INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HEPATITIS B REACTIVATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HERPES OPHTHALMIC	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES SIMPLEX	< 65	1564	87,7	7	0,4	1601	87,9	10	0,6	0,72		Algorithm converged.	0,27	1,88	-0,002		Algorithm converged.	-0,007	0,003	0,72		Algorithm converged.	0,27	1,88	0,4977	-	1,40		Algorithm converged.	0,53	3,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES VIRUS INFECTION	< 65	1564	87,7	15	1,0	1601	87,9	10	0,6	1,54		Algorithm converged.	0,69	3,44	0,003		Algorithm converged.	-0,003	0,010	1,54		Algorithm converged.	0,69	3,41	0,2917	-	0,65		Algorithm converged.	0,29	1,45
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	< 65	1564	87,7	28	1,8	1601	87,9	45	2,8	0,63		Algorithm converged.	0,39	1,02	-0,010		Algorithm converged.	-0,021	0,000	0,64		Algorithm converged.	0,40	1,02	0,0581	0,0730	1,57		Algorithm converged.	0,98	2,50
		>= 65	219	12,3	9	4,1	221	12,1	5	2,3	1,85		Algorithm converged.	0,61	5,62	0,018		Algorithm converged.	-0,014	0,051	1,82		Algorithm converged.	0,62	5,33	0,2774		0,55		Algorithm converged.	0,19	1,62
	HORDEOLUM	< 65	1564	87,7	14	0,9	1601	87,9	19	1,2	0,75		Algorithm converged.	0,38	1,51	-0,003		Algorithm converged.	-0,010	0,004	0,75		Algorithm converged.	0,38	1,50	0,4210	-	1,33		Algorithm converged.	0,67	2,63
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	IMPETIGO	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE CELLULITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED BITE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	< 65	1564	87,7	34	2,2	1601	87,9	22	1,4	1,59		Algorithm converged.	0,93	2,74	0,008		Algorithm converged.	-0,001	0,017	1,58		Algorithm converged.	0,93	2,69	0,0909	-	0,63		Algorithm converged.	0,37	1,08
		>= 65	219	12,3	0	0,0	221	12,1	5	2,3	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFLUENZA	< 65	1564	87,7	39	2,5	1601	87,9	55	3,4	0,72		Algorithm converged.	0,47	1,09	-0,009		Algorithm converged.	-0,021	0,002	0,73		Algorithm converged.	0,48	1,09	0,1204	0,5870	1,38		Algorithm converged.	0,92	2,06
		>= 65	219	12,3	6	2,7	221	12,1	6	2,7	1,01		Algorithm converged.	0,32	3,18	0,000		Algorithm converged.	-0,030	0,031	1,01		Algorithm converged.	0,33	3,08	0,9873		0,99		Algorithm converged.	0,32	3,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LABYRINTHITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGITIS	< 65	1564	87,7	11	0,7	1601	87,9	15	0,9	0,75		Algorithm converged.	0,34	1,64	-0,002		Algorithm converged.	-0,009	0,004	0,75		Algorithm converged.	0,35	1,63	0,4682	-	1,33		Algorithm converged.	0,61	2,89
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	LARYNGOPHARYNGITIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP INFECTION	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOCALISED INFECTION	< 65	1564	87,7	15	1,0	1601	87,9	7	0,4	2,21		Algorithm converged.	0,90	5,42	0,005		Algorithm converged.	-0,001	0,011	2,19		Algorithm converged.	0,90	5,37	0,0852	-	0,46		Algorithm converged.	0,19	1,12
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	LOWER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	17	1,1	1601	87,9	13	0,8	1,34		Algorithm converged.	0,65	2,77	0,003		Algorithm converged.	-0,004	0,010	1,34		Algorithm converged.	0,65	2,75	0,4264	-	0,75		Algorithm converged.	0,36	1,53
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPH GLAND INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	< 65	1564	87,7	17	1,1	1601	87,9	17	1,1	1,02		Algorithm converged.	0,52	2,01	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,52	2,00	0,9454	-	0,98		Algorithm converged.	0,50	1,91
		>= 65	219	12,3	5	2,3	221	12,1	1	0,5	5,14		Algorithm converged.	0,60	44,36	0,018		Algorithm converged.	-0,003	0,040	5,05		Algorithm converged.	0,59	42,84	0,1380		0,20		Algorithm converged.	0,02	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MORAXELLA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	7	0,4	0,44		Algorithm converged.	0,11	1,70	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2319	-	2,28		Algorithm converged.	0,59	8,80
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	MUMPS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYCOBACTERIAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	MYRINGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL INFECTION	< 65	1564	87,7	20	1,3	1601	87,9	17	1,1	1,21		Algorithm converged.	0,63	2,31	0,002		Algorithm converged.	-0,005	0,010	1,20		Algorithm converged.	0,63	2,29	0,5708	-	0,83		Algorithm converged.	0,44	1,58
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83
	NASAL HERPES	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL VESTIBULITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASOPHARYNGITIS	< 65	1564	87,7	213	13,6	1601	87,9	191	11,9	1,16		Algorithm converged.	0,94	1,43	0,017		Algorithm converged.	-0,006	0,040	1,14		Algorithm converged.	0,95	1,37	0,1550	0,4764	0,88		Algorithm converged.	0,73	1,05
		>= 65	219	12,3	21	9,6	221	12,1	23	10,4	0,91		Algorithm converged.	0,49	1,70	-0,008		Algorithm converged.	-0,064	0,048	0,92		Algorithm converged.	0,53	1,62	0,7749		1,09		Algorithm converged.	0,62	1,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OESOPHAGEAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OMPHALITIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOMYCOSIS	< 65	1564	87,7	10	0,6	1601	87,9	3	0,2	3,43		Algorithm converged.	0,94	12,48	0,005		Algorithm converged.	0,000	0,009	3,41		Algorithm converged.	0,94	12,37	0,0619	-	0,29		Algorithm converged.	0,08	1,06
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ORAL CANDIDIASIS	< 65	1564	87,7	21	1,3	1601	87,9	30	1,9	0,71		Algorithm converged.	0,41	1,25	-0,005		Algorithm converged.	-0,014	0,003	0,72		Algorithm converged.	0,41	1,25	0,2377	-	1,40		Algorithm converged.	0,80	2,43
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	ORAL FUNGAL INFECTION	< 65	1564	87,7	9	0,6	1601	87,9	6	0,4	1,54		Algorithm converged.	0,55	4,33	0,002		Algorithm converged.	-0,003	0,007	1,54		Algorithm converged.	0,55	4,30	0,4148	-	0,65		Algorithm converged.	0,23	1,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL HERPES	< 65	1564	87,7	26	1,7	1601	87,9	29	1,8	0,92		Algorithm converged.	0,54	1,56	-0,001		Algorithm converged.	-0,011	0,008	0,92		Algorithm converged.	0,54	1,55	0,7486	-	1,09		Algorithm converged.	0,64	1,84
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28
	ORAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OROPHARYNGITIS FUNGAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	OTITIS EXTERNA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA	< 65	1564	87,7	3	0,2	1601	87,9	6	0,4	0,51		Algorithm converged.	0,13	2,05	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,13	2,04	0,3429	-	1,95		Algorithm converged.	0,49	7,80
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	OTITIS MEDIA BACTERIAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLOMA VIRAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARONYCHIA	< 65	1564	87,7	61	3,9	1601	87,9	32	2,0	1,99		Algorithm converged.	1,29	3,07	0,019		Algorithm converged.	0,007	0,031	1,95		Algorithm converged.	1,28	2,98	0,0019	0,0967	0,51		Algorithm converged.	0,34	0,78
		>= 65	219	12,3	6	2,7	221	12,1	8	3,6	0,75		Algorithm converged.	0,26	2,20	-0,009		Algorithm converged.	-0,042	0,024	0,76		Algorithm converged.	0,27	2,15	0,6002		1,32		Algorithm converged.	0,47	3,75
	PAROTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC INFLAMMATORY DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERICORONITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4	1,71		Algorithm converged.	0,62	4,72	0,003		Algorithm converged.	-0,002	0,008	1,71		Algorithm converged.	0,62	4,68	0,2998	-	0,59		Algorithm converged.	0,21	1,61
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL NERVE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276222 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERITONSILLITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERTUSSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHARYNGITIS	< 65	1564	87,7	69	4,4	1601	87,9	63	3,9	1,13		Algorithm converged.	0,79	1,60	0,005		Algorithm converged.	-0,009	0,019	1,12		Algorithm converged.	0,80	1,57	0,5026	-	0,89		Algorithm converged.	0,64	1,25
		>= 65	219	12,3	4	1,8	221	12,1	5	2,3	0,80		Algorithm converged.	0,21	3,03	-0,004		Algorithm converged.	-0,031	0,022	0,81		Algorithm converged.	0,22	2,97	0,7472		1,24		Algorithm converged.	0,34	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGITIS BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS STREPTOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGOTONSILLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PILONIDAL CYST	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	< 65	1564	87,7	35	2,2	1601	87,9	28	1,7	1,29		Algorithm converged.	0,78	2,12	0,005		Algorithm converged.	-0,005	0,015	1,28		Algorithm converged.	0,78	2,09	0,3261	0,3585	0,78		Algorithm converged.	0,48	1,28
		>= 65	219	12,3	5	2,3	221	12,1	7	3,2	0,71		Algorithm converged.	0,22	2,29	-0,009		Algorithm converged.	-0,039	0,022	0,72		Algorithm converged.	0,23	2,24	0,5709		1,39		Algorithm converged.	0,45	4,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA ASPIRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA CHLAMYDIAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE WOUND INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMEMBRANOUS COLITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMONAS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY TUBERCULOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PULPITIS DENTAL	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PURULENT DISCHARGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PUSTULE	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS ACUTE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYODERMA STREPTOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION SITE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH PUSTULAR	< 65	1564	87,7	17	1,1	1601	87,9	10	0,6	1,75		Algorithm converged.	0,80	3,83	0,005		Algorithm converged.	-0,002	0,011	1,74		Algorithm converged.	0,80	3,79	0,1628	-	0,57		Algorithm converged.	0,26	1,25

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	< 65	1564	87,7	21	1,3	1601	87,9	14	0,9	1,54		Algorithm converged.	0,78	3,04	0,005		Algorithm converged.	-0,003	0,012	1,54		Algorithm converged.	0,78	3,01	0,2115	-	0,65		Algorithm converged.	0,33	1,28
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RESPIRATORY TRACT INFECTION VIRAL	< 65	1564	87,7	10	0,6	1601	87,9	14	0,9	0,73		Algorithm converged.	0,32	1,65	-0,002		Algorithm converged.	-0,008	0,004	0,73		Algorithm converged.	0,33	1,64	0,4479	-	1,37		Algorithm converged.	0,61	3,07
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHINITIS	< 65	1564	87,7	88	5,6	1601	87,9	73	4,6	1,25		Algorithm converged.	0,91	1,72	0,011		Algorithm converged.	-0,005	0,026	1,23		Algorithm converged.	0,91	1,67	0,1729	0,2040	0,81		Algorithm converged.	0,60	1,10
		>= 65	219	12,3	17	7,8	221	12,1	8	3,6	2,24		Algorithm converged.	0,95	5,31	0,041		Algorithm converged.	-0,002	0,085	2,14		Algorithm converged.	0,95	4,87	0,0680		0,47		Algorithm converged.	0,21	1,06
	RHINOVIRUS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEBACEOUS GLAND INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	< 65	1564	87,7	3	0,2	1601	87,9	7	0,4	0,44		Algorithm converged.	0,11	1,70	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2319	-	2,28		Algorithm converged.	0,59	8,80
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERRATIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	< 65	1564	87,7	40	2,6	1601	87,9	44	2,7	0,93		Algorithm converged.	0,60	1,43	-0,002		Algorithm converged.	-0,013	0,009	0,93		Algorithm converged.	0,61	1,42	0,7386	0,9011	1,07		Algorithm converged.	0,70	1,64

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	SINUSITIS BACTERIAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN CANDIDA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	< 65	1564	87,7	36	2,3	1601	87,9	26	1,6	1,43		Algorithm converged.	0,86	2,38	0,007		Algorithm converged.	-0,003	0,016	1,42		Algorithm converged.	0,86	2,34	0,1712	-	0,71		Algorithm converged.	0,43	1,16
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	< 65	1564	87,7	6	0,4	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,025	*	WARNING: The relative Hessian convergence criterion of 28.691372773 is greater than the limit of 0.0001. The convergence is questionable.	-0,027	0,077	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963341 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STREPTOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRONGYLOIDIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCUTANEOUS ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TINEA CAPITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA CRURIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA PEDIS	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	TONSILLITIS	< 65	1564	87,7	8	0,5	1601	87,9	12	0,7	0,68		Algorithm converged.	0,28	1,67	-0,002		Algorithm converged.	-0,008	0,003	0,68		Algorithm converged.	0,28	1,66	0,4011	-	1,47		Algorithm converged.	0,60	3,57
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TOOTH ABSCESS	< 65	1564	87,7	11	0,7	1601	87,9	9	0,6	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,007	1,25		Algorithm converged.	0,52	3,01	0,6170	-	0,80		Algorithm converged.	0,33	1,92
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	TOOTH INFECTION	< 65	1564	87,7	11	0,7	1601	87,9	13	0,8	0,87		Algorithm converged.	0,39	1,94	-0,001		Algorithm converged.	-0,007	0,005	0,87		Algorithm converged.	0,39	1,93	0,7248	-	1,15		Algorithm converged.	0,52	2,57
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	TRACHEITIS	< 65	1564	87,7	8	0,5	1601	87,9	7	0,4	1,17		Algorithm converged.	0,42	3,24	0,001		Algorithm converged.	-0,004	0,006	1,17		Algorithm converged.	0,43	3,22	0,7612	-	0,85		Algorithm converged.	0,31	2,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRACHEOBRONCHITIS	< 65	1564	87,7	5	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICHOPHYTOSIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	130	8,3	1601	87,9	124	7,7	1,08		Algorithm converged.	0,84	1,40	0,006		Algorithm converged.	-0,013	0,025	1,07		Algorithm converged.	0,85	1,36	0,5574	0,4321	0,93		Algorithm converged.	0,74	1,18
		>= 65	219	12,3	9	4,1	221	12,1	12	5,4	0,75		Algorithm converged.	0,31	1,81	-0,013		Algorithm converged.	-0,053	0,027	0,76		Algorithm converged.	0,33	1,76	0,5176		1,32		Algorithm converged.	0,57	3,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URETHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION	< 65	1564	87,7	115	7,4	1601	87,9	99	6,2	1,20		Algorithm converged.	0,91	1,59	0,012		Algorithm converged.	-0,006	0,029	1,19		Algorithm converged.	0,92	1,54	0,1909	0,3391	0,84		Algorithm converged.	0,65	1,09
		>= 65	219	12,3	24	11,0	221	12,1	27	12,2	0,88		Algorithm converged.	0,49	1,59	-0,013		Algorithm converged.	-0,072	0,047	0,90		Algorithm converged.	0,53	1,50	0,6804		1,11		Algorithm converged.	0,66	1,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION ENTEROCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION STAPHYLOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL ABSCESS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL INFECTION	< 65	1564	87,7	20	1,3	1601	87,9	26	1,6	0,78		Algorithm converged.	0,44	1,41	-0,003		Algorithm converged.	-0,012	0,005	0,79		Algorithm converged.	0,44	1,40	0,4183	-	1,27		Algorithm converged.	0,71	2,27
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	VAGINITIS GARDNERELLA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VARICELLA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VARICELLA ZOSTER VIRUS INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	10	0,6	0,41		Algorithm converged.	0,13	1,30	-0,004		Algorithm converged.	-0,008	0,001	0,41		Algorithm converged.	0,13	1,30	0,1305	-	2,44		Algorithm converged.	0,77	7,77
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR NEURONITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VESTIBULITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VIRAL INFECTION	< 65	1564	87,7	16	1,0	1601	87,9	10	0,6	1,64		Algorithm converged.	0,74	3,63	0,004		Algorithm converged.	-0,002	0,010	1,64		Algorithm converged.	0,75	3,60	0,2192	-	0,61		Algorithm converged.	0,28	1,34
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL PHARYNGITIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL RASH	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL RHINITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL SINUSITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL TRACHEITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	8	0,5	0,13		Algorithm converged.	0,02	1,02	-0,004		Algorithm converged.	-0,008	-0,001	0,13		Algorithm converged.	0,02	1,02	0,0524	-	7,82		Algorithm converged.	0,98	62,41
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL CANDIDIASIS	< 65	1564	87,7	17	1,1	1601	87,9	5	0,3	3,51		Algorithm converged.	1,29	9,53	0,008		Algorithm converged.	0,002	0,014	3,48		Algorithm converged.	1,29	9,41	0,0140	-	0,29		Algorithm converged.	0,11	0,78
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	VULVOVAGINAL MYCOTIC INFECTION	< 65	1564	87,7	22	1,4	1601	87,9	13	0,8	1,74		Algorithm converged.	0,87	3,47	0,006		Algorithm converged.	-0,001	0,013	1,73		Algorithm converged.	0,88	3,43	0,1144	-	0,58		Algorithm converged.	0,29	1,14
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	VULVOVAGINITIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WOUND ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION	< 65	1564	87,7	12	0,8	1601	87,9	10	0,6	1,23		Algorithm converged.	0,53	2,86	0,001		Algorithm converged.	-0,004	0,007	1,23		Algorithm converged.	0,53	2,83	0,6297	-	0,81		Algorithm converged.	0,35	1,88
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WOUND INFECTION STAPHYLOCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	413	26,4	1601	87,9	387	24,2	1,13		Algorithm converged.	0,96	1,32	0,022		Algorithm converged.	-0,008	0,053	1,09		Algorithm converged.	0,97	1,23	0,1484	0,6321	0,92		Algorithm converged.	0,81	1,03
		>= 65	219	12,3	61	27,9	221	12,1	61	27,6	1,01		Algorithm converged.	0,67	1,54	0,003		Algorithm converged.	-0,081	0,086	1,01		Algorithm converged.	0,75	1,36	0,9529		0,99		Algorithm converged.	0,73	1,34
	ACCIDENTAL OVERDOSE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANIMAL BITE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANIMAL SCRATCH	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANKLE FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ARTHROPOD BITE	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ARTHROPOD STING	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AVULSION FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY WEB SYNDROME	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BITE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PROCEDURAL COMPLICATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURN ORAL CAVITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BURNS SECOND DEGREE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL BURN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEMICAL BURNS OF EYE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL PHLEBITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHILLBLAINS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONCUSSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONTUSION	< 65	1564	87,7	16	1,0	1601	87,9	15	0,9	1,09		Algorithm converged.	0,54	2,22	0,001		Algorithm converged.	-0,006	0,008	1,09		Algorithm converged.	0,54	2,20	0,8058	-	0,92		Algorithm converged.	0,45	1,85
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DENTAL RESTORATION FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPICONDYLITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHAR	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE CONTUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE INJURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FACIAL BONES FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FALL	< 65	1564	87,7	8	0,5	1601	87,9	12	0,7	0,68		Algorithm converged.	0,28	1,67	-0,002		Algorithm converged.	-0,008	0,003	0,68		Algorithm converged.	0,28	1,66	0,4011	-	1,47		Algorithm converged.	0,60	3,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	FEMORAL NECK FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOOT FRACTURE	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FOREIGN BODY IN THROAT	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FRACTURED SACRUM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL INJURY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GINGIVAL INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients	Patients with Event	Patients	Patients with Event	Odds Ratio					Absolute Risk Difference							Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ILIUM FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE COMPLICATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE PAIN	< 65	1564	87,7	6	0,4	1601	87,9	11	0,7	0,56		Algorithm converged.	0,21	1,51	-0,003		Algorithm converged.	-0,008	0,002	0,56		Algorithm converged.	0,21	1,51	0,2497	-	1,79		Algorithm converged.	0,66	4,83
		>= 65	219	12,3	5	2,3	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	INFUSION RELATED REACTION	< 65	1564	87,7	64	4,1	1601	87,9	57	3,6	1,16		Algorithm converged.	0,80	1,66	0,005		Algorithm converged.	-0,008	0,019	1,15		Algorithm converged.	0,81	1,63	0,4358	0,6243	0,87		Algorithm converged.	0,61	1,23
		>= 65	219	12,3	7	3,2	221	12,1	8	3,6	0,88		Algorithm converged.	0,31	2,47	-0,004		Algorithm converged.	-0,038	0,030	0,88		Algorithm converged.	0,33	2,39	0,8067		1,13		Algorithm converged.	0,42	3,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	JOINT INJURY	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LIGAMENT SPRAIN	< 65	1564	87,7	7	0,4	1601	87,9	9	0,6	0,80		Algorithm converged.	0,30	2,14	-0,001		Algorithm converged.	-0,006	0,004	0,80		Algorithm converged.	0,30	2,13	0,6502	-	1,26		Algorithm converged.	0,47	3,36
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIMB INJURY	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER LIMB FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE RUPTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE STRAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL INJURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOCONIOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX TRAUMATIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POISONING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL SWELLING	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTMASTECTOMY LYMPHOEDEMA SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL DIZZINESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	< 65	1564	87,7	9	0,6	1601	87,9	14	0,9	0,66		Algorithm converged.	0,28	1,52	-0,003		Algorithm converged.	-0,009	0,003	0,66		Algorithm converged.	0,29	1,52	0,3257	-	1,52		Algorithm converged.	0,66	3,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PULMONARY RADIATION INJURY	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION ASSOCIATED PAIN	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	RADIATION INJURY	< 65	1564	87,7	37	2,4	1601	87,9	34	2,1	1,12		Algorithm converged.	0,70	1,79	0,002		Algorithm converged.	-0,008	0,013	1,11		Algorithm converged.	0,70	1,77	0,6459	0,6709	0,90		Algorithm converged.	0,57	1,42
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION NECROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION NEUROPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION OESOPHAGITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION PNEUMONITIS	< 65	1564	87,7	9	0,6	1601	87,9	4	0,2	2,31		Algorithm converged.	0,71	7,52	0,003		Algorithm converged.	-0,001	0,008	2,30		Algorithm converged.	0,71	7,46	0,1643	-	0,43		Algorithm converged.	0,13	1,41
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	RADIATION SKIN INJURY	< 65	1564	87,7	217	13,9	1601	87,9	174	10,9	1,32		Algorithm converged.	1,07	1,63	0,030		Algorithm converged.	0,007	0,053	1,28		Algorithm converged.	1,06	1,54	0,0104	0,1990	0,78		Algorithm converged.	0,65	0,94
		>= 65	219	12,3	27	12,3	221	12,1	30	13,6	0,90		Algorithm converged.	0,51	1,56	-0,012		Algorithm converged.	-0,075	0,050	0,91		Algorithm converged.	0,56	1,48	0,6974		1,10		Algorithm converged.	0,68	1,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECALL PHENOMENON	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RIB FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ROAD TRAFFIC ACCIDENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCAR	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SEROMA	< 65	1564	87,7	8	0,5	1601	87,9	13	0,8	0,63		Algorithm converged.	0,26	1,52	-0,003		Algorithm converged.	-0,009	0,003	0,63		Algorithm converged.	0,26	1,52	0,3022	-	1,59		Algorithm converged.	0,66	3,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN ABRASION	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	SKIN INJURY	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LACERATION	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STRESS FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDON INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDON RUPTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	THERMAL BURN	< 65	1564	87,7	12	0,8	1601	87,9	11	0,7	1,12		Algorithm converged.	0,49	2,54	0,001		Algorithm converged.	-0,005	0,007	1,12		Algorithm converged.	0,49	2,52	0,7907	-	0,90		Algorithm converged.	0,40	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THORACIC VERTEBRAL FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TIBIA FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH FRACTURE	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963577 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TOXICITY TO VARIOUS AGENTS	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSFUSION REACTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRAUMATIC HAEMATOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ULNA FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER LIMB FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR ACCESS COMPLICATION	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENOUS INJURY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIITH NERVE INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL INJURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	WOUND COMPLICATION	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WOUND DEHISCENCE	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND SECRETION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WRIST FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	< 65	1564	87,7	656	41,9	1601	87,9	720	45,0	0,88		Algorithm converged.	0,77	1,02	-0,030		Algorithm converged.	-0,065	0,004	0,93		Algorithm converged.	0,86	1,01	0,0861	0,0432	1,07		Algorithm converged.	0,99	1,16
		>= 65	219	12,3	99	45,2	221	12,1	84	38,0	1,35		Algorithm converged.	0,92	1,97	0,072		Algorithm converged.	-0,020	0,164	1,19		Algorithm converged.	0,95	1,49	0,1271		0,84		Algorithm converged.	0,67	1,05
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	164	10,5	1601	87,9	185	11,6	0,90		Algorithm converged.	0,72	1,12	-0,011		Algorithm converged.	-0,033	0,011	0,91		Algorithm converged.	0,74	1,11	0,3372	0,6443	1,10		Algorithm converged.	0,90	1,34
		>= 65	219	12,3	12	5,5	221	12,1	11	5,0	1,11		Algorithm converged.	0,48	2,56	0,005		Algorithm converged.	-0,037	0,047	1,10		Algorithm converged.	0,50	2,44	0,8131		0,91		Algorithm converged.	0,41	2,01
	ASPARTATE AMINOTRANSFERASE	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	112	7,2	1601	87,9	122	7,6	0,94		Algorithm converged.	0,72	1,22	-0,005		Algorithm converged.	-0,023	0,014	0,94		Algorithm converged.	0,73	1,20	0,6217	0,9053	1,06		Algorithm converged.	0,83	1,36
		>= 65	219	12,3	7	3,2	221	12,1	8	3,6	0,88		Algorithm converged.	0,31	2,47	-0,004		Algorithm converged.	-0,038	0,030	0,88		Algorithm converged.	0,33	2,39	0,8067		1,13		Algorithm converged.	0,42	3,07
	BILIRUBIN CONJUGATED INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD ALKALINE PHOSPHATASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	1564	87,7	30	1,9	1601	87,9	36	2,2	0,85		Algorithm converged.	0,52	1,39	-0,003		Algorithm converged.	-0,013	0,007	0,85		Algorithm converged.	0,53	1,38	0,5159	-	1,17		Algorithm converged.	0,73	1,89
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18
	BLOOD BILIRUBIN DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	< 65	1564	87,7	14	0,9	1601	87,9	10	0,6	1,44		Algorithm converged.	0,64	3,24	0,003		Algorithm converged.	-0,003	0,009	1,43		Algorithm converged.	0,64	3,22	0,3830	-	0,70		Algorithm converged.	0,31	1,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN UNCONJUGATED INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CALCIUM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CALCIUM DECREASED	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHLORIDE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	< 65	1564	87,7	8	0,5	1601	87,9	11	0,7	0,74		Algorithm converged.	0,30	1,85	-0,002		Algorithm converged.	-0,007	0,004	0,74		Algorithm converged.	0,30	1,85	0,5242	-	1,34		Algorithm converged.	0,54	3,33
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATINE PHOSPHOKINASE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	< 65	1564	87,7	12	0,8	1601	87,9	4	0,2	3,09		Algorithm converged.	0,99	9,59	0,005		Algorithm converged.	0,000	0,010	3,07		Algorithm converged.	0,99	9,50	0,0515	-	0,33		Algorithm converged.	0,11	1,01
		>= 65	219	12,3	1	0,5	221	12,1	5	2,3	0,20		Algorithm converged.	0,02	1,71	-0,018		Algorithm converged.	-0,040	0,003	0,20		Algorithm converged.	0,02	1,71	0,1425		4,95		Algorithm converged.	0,58	42,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD GLUCOSE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD LACTATE DEHYDROGENASE DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	1564	87,7	26	1,7	1601	87,9	18	1,1	1,49		Algorithm converged.	0,81	2,72	0,005		Algorithm converged.	-0,003	0,014	1,48		Algorithm converged.	0,81	2,69	0,1991	-	0,68		Algorithm converged.	0,37	1,23
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM DECREASED	< 65	1564	87,7	8	0,5	1601	87,9	7	0,4	1,17		Algorithm converged.	0,42	3,24	0,001		Algorithm converged.	-0,004	0,006	1,17		Algorithm converged.	0,43	3,22	0,7612	-	0,85		Algorithm converged.	0,31	2,35
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	BLOOD MAGNESIUM INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PHOSPHORUS DECREASED	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PHOSPHORUS INCREASED	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD POTASSIUM DECREASED	< 65	1564	87,7	6	0,4	1601	87,9	3	0,2	2,05		Algorithm converged.	0,51	8,22	0,002		Algorithm converged.	-0,002	0,006	2,05		Algorithm converged.	0,51	8,17	0,3103	-	0,49		Algorithm converged.	0,12	1,95
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD POTASSIUM INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DIASTOLIC DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DIASTOLIC INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE INCREASED	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD SODIUM DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD SODIUM INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD UREA DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD UREA INCREASED	< 65	1564	87,7	5	0,3	1601	87,9	7	0,4	0,73		Algorithm converged.	0,23	2,31	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5922	-	1,37		Algorithm converged.	0,43	4,30
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD URIC ACID INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BLOOD URINE PRESENT	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BODY TEMPERATURE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BREATH SOUNDS ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	C-REACTIVE PROTEIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARBOHYDRATE ANTIGEN 125 INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARBOHYDRATE ANTIGEN 15-3 INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC MURMUR	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM TEST POSITIVE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CREATININE RENAL CLEARANCE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DELTARETROVIRUS TEST POSITIVE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECHOCARDIOGRAM ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	< 65	1564	87,7	69	4,4	1601	87,9	99	6,2	0,70		Algorithm converged.	0,51	0,96	-0,018		Algorithm converged.	-0,033	-0,002	0,71		Algorithm converged.	0,53	0,96	0,0271	0,0768	1,40		Algorithm converged.	1,04	1,89
		>= 65	219	12,3	18	8,2	221	12,1	13	5,9	1,43		Algorithm converged.	0,68	3,00	0,023		Algorithm converged.	-0,024	0,071	1,40		Algorithm converged.	0,70	2,78	0,3409		0,72		Algorithm converged.	0,36	1,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROCARDIOGRAM QT PROLONGED	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ELECTROCARDIOGRAM ST-T CHANGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ELECTROCARDIOGRAM T WAVE ABNORMAL	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM T WAVE INVERSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHIL COUNT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHIL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FORCED EXPIRATORY VOLUME DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	1564	87,7	16	1,0	1601	87,9	33	2,1	0,49		Algorithm converged.	0,27	0,90	-0,010		Algorithm converged.	-0,019	-0,002	0,50		Algorithm converged.	0,27	0,90	0,0206	-	2,01		Algorithm converged.	1,11	3,65
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	GLOMERULAR FILTRATION RATE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GLYCOSYLATED HAEMOGLOBIN INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMATOCRIT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOGLOBIN	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HAEMOGLOBIN DECREASED	< 65	1564	87,7	50	3,2	1601	87,9	55	3,4	0,93		Algorithm converged.	0,63	1,37	-0,002		Algorithm converged.	-0,015	0,010	0,93		Algorithm converged.	0,64	1,36	0,7081	-	1,07		Algorithm converged.	0,74	1,57
		>= 65	219	12,3	5	2,3	221	12,1	4	1,8	1,27		Algorithm converged.	0,34	4,78	0,005		Algorithm converged.	-0,022	0,031	1,26		Algorithm converged.	0,34	4,64	0,7265		0,79		Algorithm converged.	0,22	2,91
	HAEMOGLOBIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAPTOGLOBIN DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEART RATE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HELICOBACTER TEST POSITIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC ENZYME ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC ENZYME INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HUMAN CHORIONIC GONADOTROPIN INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTE COUNT DECREASED	< 65	1564	87,7	12	0,8	1601	87,9	8	0,5	1,54		Algorithm converged.	0,63	3,78	0,003		Algorithm converged.	-0,003	0,008	1,54		Algorithm converged.	0,63	3,75	0,3460	-	0,65		Algorithm converged.	0,27	1,59
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	LYMPHOCYTE COUNT INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MEGAKARYOCYTES ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAMYELOCYTE COUNT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONONUCLEAR CELL COUNT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	< 65	1564	87,7	4	0,3	1601	87,9	6	0,4	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,005	0,003	0,68		Algorithm converged.	0,19	2,41	0,5533	-	1,47		Algorithm converged.	0,41	5,18
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	234	15,0	1601	87,9	238	14,9	1,01		Algorithm converged.	0,83	1,23	0,001		Algorithm converged.	-0,024	0,026	1,01		Algorithm converged.	0,85	1,19	0,9396	0,8834	0,99		Algorithm converged.	0,84	1,17
		>= 65	219	12,3	28	12,8	221	12,1	27	12,2	1,05		Algorithm converged.	0,60	1,85	0,006		Algorithm converged.	-0,056	0,067	1,05		Algorithm converged.	0,64	1,72	0,8570		0,96		Algorithm converged.	0,58	1,57
	NEUTROPHIL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHYSICAL EXAMINATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHYSICAL EXAMINATION ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	< 65	1564	87,7	51	3,3	1601	87,9	54	3,4	0,97		Algorithm converged.	0,65	1,43	-0,001		Algorithm converged.	-0,014	0,011	0,97		Algorithm converged.	0,66	1,41	0,8604	0,6234	1,03		Algorithm converged.	0,71	1,51
		>= 65	219	12,3	12	5,5	221	12,1	10	4,5	1,22		Algorithm converged.	0,52	2,89	0,010		Algorithm converged.	-0,031	0,050	1,21		Algorithm converged.	0,53	2,74	0,6466		0,83		Algorithm converged.	0,36	1,87
	PLATELET COUNT INCREASED	< 65	1564	87,7	9	0,6	1601	87,9	8	0,5	1,15		Algorithm converged.	0,44	2,99	0,001		Algorithm converged.	-0,004	0,006	1,15		Algorithm converged.	0,45	2,98	0,7708	-	0,87		Algorithm converged.	0,34	2,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROTEIN TOTAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROTEIN TOTAL DECREASED	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROTEIN URINE PRESENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RED BLOOD CELL COUNT DECREASED	< 65	1564	87,7	16	1,0	1601	87,9	12	0,7	1,37		Algorithm converged.	0,65	2,90	0,003		Algorithm converged.	-0,004	0,009	1,36		Algorithm converged.	0,65	2,88	0,4133	-	0,73		Algorithm converged.	0,35	1,54
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERUM FERRITIN DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMEAR CERVIX ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID FUNCTION TEST ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID FUNCTION TEST NORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSAMINASES DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSAMINASES INCREASED	< 65	1564	87,7	17	1,1	1601	87,9	18	1,1	0,97		Algorithm converged.	0,50	1,88	0,000		Algorithm converged.	-0,008	0,007	0,97		Algorithm converged.	0,50	1,87	0,9200	-	1,03		Algorithm converged.	0,54	2,00
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSFERRIN SATURATION DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN T INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE ANALYSIS ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE OUTPUT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN B12 DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN D DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	< 65	1564	87,7	103	6,6	1601	87,9	55	3,4	1,98		Algorithm converged.	1,42	2,77	0,032		Algorithm converged.	0,016	0,047	1,92		Algorithm converged.	1,39	2,64	<.0001	0,1082	0,52		Algorithm converged.	0,38	0,72
		>= 65	219	12,3	37	16,9	221	12,1	11	5,0	3,88		Algorithm converged.	1,92	7,83	0,119		Algorithm converged.	0,062	0,176	3,39		Algorithm converged.	1,78	6,48	0,0002		0,29		Algorithm converged.	0,15	0,56
	WEIGHT INCREASED	< 65	1564	87,7	44	2,8	1601	87,9	101	6,3	0,43		Algorithm converged.	0,30	0,62	-0,035		Algorithm converged.	-0,049	-0,020	0,45		Algorithm converged.	0,32	0,63	<.0001	-	2,24		Algorithm converged.	1,58	3,17
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	WHITE BLOOD CELL COUNT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	180	11,5	1601	87,9	157	9,8	1,20		Algorithm converged.	0,95	1,50	0,017		Algorithm converged.	-0,004	0,039	1,17		Algorithm converged.	0,96	1,44	0,1210	0,1545	0,85		Algorithm converged.	0,70	1,04
		>= 65	219	12,3	23	10,5	221	12,1	12	5,4	2,04		Algorithm converged.	0,99	4,22	0,051		Algorithm converged.	0,000	0,101	1,93		Algorithm converged.	0,99	3,79	0,0545		0,52		Algorithm converged.	0,26	1,01
	WHITE BLOOD CELL COUNT INCREASED	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	514	32,9	1601	87,9	476	29,7	1,16		Algorithm converged.	1,00	1,34	0,031		Algorithm converged.	-0,001	0,064	1,11		Algorithm converged.	1,00	1,23	0,0575	0,0278	0,90		Algorithm converged.	0,82	1,00
		>= 65	219	12,3	119	54,3	221	12,1	84	38,0	1,94		Algorithm converged.	1,33	2,84	0,163		Algorithm converged.	0,071	0,255	1,43		Algorithm converged.	1,16	1,76	0,0007		0,70		Algorithm converged.	0,57	0,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACIDOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPETITE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CACHEXIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CELL DEATH	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED APPETITE	< 65	1564	87,7	341	21,8	1601	87,9	320	20,0	1,12		Algorithm converged.	0,94	1,32	0,018		Algorithm converged.	-0,010	0,046	1,09		Algorithm converged.	0,95	1,25	0,2092	0,0107	0,92		Algorithm converged.	0,80	1,05
		>= 65	219	12,3	86	39,3	221	12,1	53	24,0	2,05		Algorithm converged.	1,36	3,09	0,153		Algorithm converged.	0,067	0,239	1,64		Algorithm converged.	1,23	2,18	0,0007		0,61		Algorithm converged.	0,46	0,81
	DEHYDRATION	< 65	1564	87,7	42	2,7	1601	87,9	32	2,0	1,35		Algorithm converged.	0,85	2,15	0,007		Algorithm converged.	-0,004	0,017	1,34		Algorithm converged.	0,85	2,12	0,2029	0,1342	0,74		Algorithm converged.	0,47	1,17
		>= 65	219	12,3	19	8,7	221	12,1	7	3,2	2,90		Algorithm converged.	1,20	7,06	0,055		Algorithm converged.	0,011	0,099	2,74		Algorithm converged.	1,18	6,38	0,0196		0,37		Algorithm converged.	0,16	0,85
	DIABETES MELLITUS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETIC METABOLIC DECOMPENSATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSLIPIDAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROLYTE IMBALANCE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAILURE TO THRIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	< 65	1564	87,7	14	0,9	1601	87,9	7	0,4	2,06		Algorithm converged.	0,83	5,11	0,005		Algorithm converged.	-0,001	0,010	2,05		Algorithm converged.	0,83	5,06	0,1206	-	0,49		Algorithm converged.	0,20	1,21
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOLATE DEFICIENCY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	FOOD AVERSION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.4666615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GOUT	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOCHROMATOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERCALCAEMIA	< 65	1564	87,7	7	0,4	1601	87,9	7	0,4	1,02		Algorithm converged.	0,36	2,93	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,36	2,91	0,9650	-	0,98		Algorithm converged.	0,34	2,78
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERCHLORAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERCHOLESTEROLAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	< 65	1564	87,7	22	1,4	1601	87,9	30	1,9	0,75		Algorithm converged.	0,43	1,30	-0,005		Algorithm converged.	-0,014	0,004	0,75		Algorithm converged.	0,43	1,30	0,3030	0,9495	1,33		Algorithm converged.	0,77	2,30
		>= 65	219	12,3	5	2,3	221	12,1	7	3,2	0,71		Algorithm converged.	0,22	2,29	-0,009		Algorithm converged.	-0,039	0,022	0,72		Algorithm converged.	0,23	2,24	0,5709		1,39		Algorithm converged.	0,45	4,30
	HYPERKALAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	HYPERMAGNESAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERNATRAEMIA	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPHOSPHATAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	10	0,6	0,20		Algorithm converged.	0,04	0,93	-0,005		Algorithm converged.	-0,009	-0,001	0,20		Algorithm converged.	0,04	0,93	0,0404	-	4,88		Algorithm converged.	1,07	22,26
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERURICAEMIA	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOALBUMINAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOCALCAEMIA	< 65	1564	87,7	28	1,8	1601	87,9	18	1,1	1,60		Algorithm converged.	0,88	2,91	0,007		Algorithm converged.	-0,002	0,015	1,59		Algorithm converged.	0,88	2,87	0,1210	0,9428	0,63		Algorithm converged.	0,35	1,13
		>= 65	219	12,3	6	2,7	221	12,1	4	1,8	1,53		Algorithm converged.	0,43	5,49	0,009		Algorithm converged.	-0,019	0,037	1,51		Algorithm converged.	0,43	5,29	0,5161		0,66		Algorithm converged.	0,19	2,31
	HYPOCHLORAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOGLYCAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	< 65	1564	87,7	89	5,7	1601	87,9	66	4,1	1,40		Algorithm converged.	1,01	1,94	0,016		Algorithm converged.	0,001	0,031	1,38		Algorithm converged.	1,01	1,88	0,0420	0,8346	0,72		Algorithm converged.	0,53	0,99
		>= 65	219	12,3	19	8,7	221	12,1	15	6,8	1,30		Algorithm converged.	0,65	2,64	0,019		Algorithm converged.	-0,031	0,069	1,28		Algorithm converged.	0,67	2,45	0,4596		0,78		Algorithm converged.	0,41	1,50
	HYPOMAGNESAEMIA	< 65	1564	87,7	80	5,1	1601	87,9	53	3,3	1,57		Algorithm converged.	1,10	2,24	0,018		Algorithm converged.	0,004	0,032	1,55		Algorithm converged.	1,10	2,17	0,0121	0,0282	0,65		Algorithm converged.	0,46	0,91
		>= 65	219	12,3	27	12,3	221	12,1	7	3,2	4,30		Algorithm converged.	1,83	10,10	0,092		Algorithm converged.	0,042	0,141	3,89		Algorithm converged.	1,73	8,75	0,0010		0,26		Algorithm converged.	0,11	0,58
	HYPONATRAEMIA	< 65	1564	87,7	11	0,7	1601	87,9	17	1,1	0,66		Algorithm converged.	0,31	1,41	-0,004		Algorithm converged.	-0,010	0,003	0,66		Algorithm converged.	0,31	1,41	0,2850	-	1,51		Algorithm converged.	0,71	3,21
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	HYPOPHAGIA	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	11	0,7	1601	87,9	11	0,7	1,02		Algorithm converged.	0,44	2,37	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,45	2,35	0,9561	-	0,98		Algorithm converged.	0,42	2,25

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOPROTEINAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOVOLAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	INCREASED APPETITE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY	< 65	1564	87,7	6	0,4	1601	87,9	2	0,1	3,08		Algorithm converged.	0,62	15,28	0,003		Algorithm converged.	-0,001	0,006	3,07		Algorithm converged.	0,62	15,19	0,1690	-	0,33		Algorithm converged.	0,07	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LACTOSE INTOLERANCE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAGNESIUM DEFICIENCY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OBESITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	POLYDIPSIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TETANY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR LYSIS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TYPE 2 DIABETES MELLITUS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITAMIN B12 DEFICIENCY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN C DEFICIENCY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN D DEFICIENCY	< 65	1564	87,7	9	0,6	1601	87,9	10	0,6	0,92		Algorithm converged.	0,37	2,27	0,000		Algorithm converged.	-0,006	0,005	0,92		Algorithm converged.	0,38	2,26	0,8580	-	1,09		Algorithm converged.	0,44	2,66
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	< 65	1564	87,7	996	63,7	1601	87,9	1048	65,5	0,93		Algorithm converged.	0,80	1,07	-0,018		Algorithm converged.	-0,051	0,016	0,97		Algorithm converged.	0,92	1,02	0,2964	0,2581	1,03		Algorithm converged.	0,98	1,08
		>= 65	219	12,3	120	54,8	221	12,1	137	62,0	0,74		Algorithm converged.	0,51	1,09	-0,072		Algorithm converged.	-0,164	0,020	0,88		Algorithm converged.	0,75	1,04	0,1271		1,13		Algorithm converged.	0,97	1,33
	ARTHRALGIA	< 65	1564	87,7	478	30,6	1601	87,9	527	32,9	0,90		Algorithm converged.	0,77	1,04	-0,024		Algorithm converged.	-0,056	0,009	0,93		Algorithm converged.	0,84	1,03	0,1552	0,6269	1,08		Algorithm converged.	0,97	1,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	56	25,6	221	12,1	56	25,3	1,01		Algorithm converged.	0,66	1,55	0,002		Algorithm converged.	-0,079	0,084	1,01		Algorithm converged.	0,73	1,39	0,9556		0,99		Algorithm converged.	0,72	1,36
	ARTHRITIS	< 65	1564	87,7	11	0,7	1601	87,9	9	0,6	1,25		Algorithm converged.	0,52	3,03	0,001		Algorithm converged.	-0,004	0,007	1,25		Algorithm converged.	0,52	3,01	0,6170	-	0,80		Algorithm converged.	0,33	1,92
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	ARTHROPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY MASS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACK PAIN	< 65	1564	87,7	134	8,6	1601	87,9	168	10,5	0,80		Algorithm converged.	0,63	1,01	-0,019		Algorithm converged.	-0,040	0,001	0,82		Algorithm converged.	0,66	1,01	0,0659	0,0763	1,22		Algorithm converged.	0,99	1,52
		>= 65	219	12,3	22	10,0	221	12,1	15	6,8	1,53		Algorithm converged.	0,77	3,04	0,033		Algorithm converged.	-0,019	0,084	1,48		Algorithm converged.	0,79	2,78	0,2219		0,68		Algorithm converged.	0,36	1,27
	BONE FORMATION INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE PAIN	< 65	1564	87,7	155	9,9	1601	87,9	164	10,2	0,96		Algorithm converged.	0,76	1,22	-0,003		Algorithm converged.	-0,024	0,018	0,97		Algorithm converged.	0,79	1,19	0,7556	0,1863	1,03		Algorithm converged.	0,84	1,27
		>= 65	219	12,3	18	8,2	221	12,1	28	12,7	0,62		Algorithm converged.	0,33	1,15	-0,045		Algorithm converged.	-0,101	0,012	0,65		Algorithm converged.	0,37	1,14	0,1312		1,54		Algorithm converged.	0,88	2,70
	BURSITIS	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CHEST WALL MASS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COCCYDYNIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONNECTIVE TISSUE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COSTOCHONDRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DACTYLITIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUPUYTREN'S CONTRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXOSTOSIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FIBROMYALGIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.83427686 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLANK PAIN	< 65	1564	87,7	5	0,3	1601	87,9	10	0,6	0,51		Algorithm converged.	0,17	1,50	-0,003		Algorithm converged.	-0,008	0,002	0,51		Algorithm converged.	0,18	1,49	0,2204	-	1,95		Algorithm converged.	0,67	5,70
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	GROIN PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMARTHROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERVERTEBRAL DISC PROTRUSION	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JAW CLICKING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT INSTABILITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT LOCK	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT NOISE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT RANGE OF MOTION DECREASED	< 65	1564	87,7	10	0,6	1601	87,9	12	0,7	0,85		Algorithm converged.	0,37	1,98	-0,001		Algorithm converged.	-0,007	0,005	0,85		Algorithm converged.	0,37	1,97	0,7095	-	1,17		Algorithm converged.	0,51	2,71
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT STIFFNESS	< 65	1564	87,7	10	0,6	1601	87,9	9	0,6	1,14		Algorithm converged.	0,46	2,81	0,001		Algorithm converged.	-0,005	0,006	1,14		Algorithm converged.	0,46	2,79	0,7787	-	0,88		Algorithm converged.	0,36	2,16
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	JOINT SWELLING	< 65	1564	87,7	7	0,4	1601	87,9	8	0,5	0,90		Algorithm converged.	0,32	2,47	-0,001		Algorithm converged.	-0,005	0,004	0,90		Algorithm converged.	0,33	2,46	0,8311	-	1,12		Algorithm converged.	0,41	3,07
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIMB DISCOMFORT	< 65	1564	87,7	13	0,8	1601	87,9	14	0,9	0,95		Algorithm converged.	0,45	2,03	0,000		Algorithm converged.	-0,007	0,006	0,95		Algorithm converged.	0,45	2,02	0,8948	-	1,05		Algorithm converged.	0,50	2,23
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIMB MASS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)				Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE ATROPHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE DISCOMFORT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE RIGIDITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE SPASMS	< 65	1564	87,7	136	8,7	1601	87,9	72	4,5	2,02		Algorithm converged.	1,51	2,72	0,042		Algorithm converged.	0,025	0,059	1,93		Algorithm converged.	1,47	2,55	<.0001	0,8264	0,52		Algorithm converged.	0,39	0,68
		>= 65	219	12,3	23	10,5	221	12,1	13	5,9	1,88		Algorithm converged.	0,93	3,81	0,046		Algorithm converged.	-0,005	0,097	1,79		Algorithm converged.	0,93	3,43	0,0823		0,56		Algorithm converged.	0,29	1,08
	MUSCLE TIGHTNESS	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE TWITCHING	< 65	1564	87,7	10	0,6	1601	87,9	7	0,4	1,47		Algorithm converged.	0,56	3,86	0,002		Algorithm converged.	-0,003	0,007	1,46		Algorithm converged.	0,56	3,83	0,4394	-	0,68		Algorithm converged.	0,26	1,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULAR WEAKNESS	< 65	1564	87,7	19	1,2	1601	87,9	25	1,6	0,78		Algorithm converged.	0,43	1,41	-0,003		Algorithm converged.	-0,012	0,005	0,78		Algorithm converged.	0,43	1,41	0,4062	0,8656	1,29		Algorithm converged.	0,71	2,32
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	MUSCULOSKELETAL CHEST PAIN	< 65	1564	87,7	49	3,1	1601	87,9	49	3,1	1,02		Algorithm converged.	0,69	1,53	0,001		Algorithm converged.	-0,011	0,013	1,02		Algorithm converged.	0,69	1,51	0,9064	-	0,98		Algorithm converged.	0,66	1,44
		>= 65	219	12,3	2	0,9	221	12,1	6	2,7	0,33		Algorithm converged.	0,07	1,65	-0,018		Algorithm converged.	-0,043	0,007	0,34		Algorithm converged.	0,07	1,65	0,1791		2,97		Algorithm converged.	0,61	14,57
	MUSCULOSKELETAL DISCOMFORT	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	< 65	1564	87,7	93	5,9	1601	87,9	110	6,9	0,86		Algorithm converged.	0,64	1,14	-0,009		Algorithm converged.	-0,026	0,008	0,87		Algorithm converged.	0,66	1,13	0,2891	0,5459	1,16		Algorithm converged.	0,88	1,51
		>= 65	219	12,3	10	4,6	221	12,1	15	6,8	0,66		Algorithm converged.	0,29	1,50	-0,022		Algorithm converged.	-0,065	0,021	0,67		Algorithm converged.	0,31	1,46	0,3180		1,49		Algorithm converged.	0,68	3,24
	MUSCULOSKELETAL STIFFNESS	< 65	1564	87,7	18	1,2	1601	87,9	31	1,9	0,59		Algorithm converged.	0,33	1,06	-0,008		Algorithm converged.	-0,016	0,001	0,59		Algorithm converged.	0,33	1,06	0,0770	-	1,68		Algorithm converged.	0,95	2,99
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	MYALGIA	< 65	1564	87,7	414	26,5	1601	87,9	472	29,5	0,86		Algorithm converged.	0,74	1,01	-0,030		Algorithm converged.	-0,061	0,001	0,90		Algorithm converged.	0,80	1,00	0,0596	0,7488	1,11		Algorithm converged.	1,00	1,25
		>= 65	219	12,3	47	21,5	221	12,1	56	25,3	0,81		Algorithm converged.	0,52	1,25	-0,039		Algorithm converged.	-0,118	0,040	0,85		Algorithm converged.	0,60	1,19	0,3379		1,18		Algorithm converged.	0,84	1,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOSITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	NECK PAIN	< 65	1564	87,7	28	1,8	1601	87,9	30	1,9	0,95		Algorithm converged.	0,57	1,61	-0,001		Algorithm converged.	-0,010	0,009	0,96		Algorithm converged.	0,57	1,59	0,8609	-	1,05		Algorithm converged.	0,63	1,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91
	OSTEOARTHRITIS	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28
	OSTEONECROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OSTEOPENIA	< 65	1564	87,7	18	1,2	1601	87,9	12	0,7	1,54		Algorithm converged.	0,74	3,21	0,004		Algorithm converged.	-0,003	0,011	1,54		Algorithm converged.	0,74	3,18	0,2477	-	0,65		Algorithm converged.	0,31	1,35
		>= 65	219	12,3	4	1,8	221	12,1	1	0,5	4,09		Algorithm converged.	0,45	36,92	0,014		Algorithm converged.	-0,006	0,034	4,04		Algorithm converged.	0,45	35,83	0,2103		0,25		Algorithm converged.	0,03	2,20
	OSTEOPOROSIS	< 65	1564	87,7	22	1,4	1601	87,9	20	1,2	1,13		Algorithm converged.	0,61	2,07	0,002		Algorithm converged.	-0,006	0,010	1,13		Algorithm converged.	0,62	2,05	0,6989	-	0,89		Algorithm converged.	0,49	1,62
		>= 65	219	12,3	5	2,3	221	12,1	4	1,8	1,27		Algorithm converged.	0,34	4,78	0,005		Algorithm converged.	-0,022	0,031	1,26		Algorithm converged.	0,34	4,64	0,7265		0,79		Algorithm converged.	0,22	2,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAIN IN EXTREMITY	< 65	1564	87,7	164	10,5	1601	87,9	166	10,4	1,01		Algorithm converged.	0,81	1,27	0,001		Algorithm converged.	-0,020	0,022	1,01		Algorithm converged.	0,82	1,24	0,9139	0,0089	0,99		Algorithm converged.	0,81	1,21
		>= 65	219	12,3	17	7,8	221	12,1	36	16,3	0,43		Algorithm converged.	0,23	0,80	-0,085		Algorithm converged.	-0,145	-0,025	0,48		Algorithm converged.	0,28	0,82	0,0078		2,10		Algorithm converged.	1,22	3,62
	PAIN IN JAW	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERIARTHRITIS	< 65	1564	87,7	5	0,3	1601	87,9	2	0,1	2,56		Algorithm converged.	0,50	13,24	0,002		Algorithm converged.	-0,001	0,005	2,56		Algorithm converged.	0,50	13,17	0,2610	-	0,39		Algorithm converged.	0,08	2,01
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIOSTITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLANTAR FASCIITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POLYARTHRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSORIATIC ARTHROPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RHEUMATIC DISORDER	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROTATOR CUFF SYNDROME	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SACRAL PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SACROILIITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SJOGREN'S SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL OSTEOARTHRITIS	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL PAIN	< 65	1564	87,7	8	0,5	1601	87,9	8	0,5	1,02		Algorithm converged.	0,38	2,73	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,39	2,72	0,9626	-	0,98		Algorithm converged.	0,37	2,60
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	SPINAL STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SYNOVIAL CYST	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SYSTEMIC LUPUS ERYTHEMATOSUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TEMPOROMANDIBULAR JOINT SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TENDINOUS CONTRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDON DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TENDON PAIN	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TENDONITIS	< 65	1564	87,7	9	0,6	1601	87,9	7	0,4	1,32		Algorithm converged.	0,49	3,55	0,001		Algorithm converged.	-0,004	0,006	1,32		Algorithm converged.	0,49	3,53	0,5848	-	0,76		Algorithm converged.	0,28	2,04
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENOSYNOVITIS	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1	5,13		Algorithm converged.	0,60	43,97	0,003		Algorithm converged.	0,000	0,006	5,12		Algorithm converged.	0,60	43,76	0,1359	-	0,20		Algorithm converged.	0,02	1,67
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENOSYNOVITIS STENOSANS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TORTICOLLIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRIGGER FINGER	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	TRISMUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WINGED SCAPULA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	19	1,2	1601	87,9	30	1,9	0,64		Algorithm converged.	0,36	1,15	-0,007		Algorithm converged.	-0,015	0,002	0,65		Algorithm converged.	0,37	1,15	0,1365	0,5791	1,54		Algorithm converged.	0,87	2,73
		>= 65	219	12,3	3	1,4	221	12,1	7	3,2	0,42		Algorithm converged.	0,11	1,66	-0,018		Algorithm converged.	-0,046	0,010	0,43		Algorithm converged.	0,11	1,65	0,2200		2,31		Algorithm converged.	0,61	8,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACROCHORDON	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYELOID LEUKAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANOGENITAL WARTS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BASAL CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BENIGN BREAST NEOPLASM	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BENIGN NEOPLASM OF LACRIMAL DUCT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST CANCER IN SITU	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CANCER FATIGUE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID TUMOUR	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FIBROADENOMA OF BREAST	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FIBROMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMANGIOMA OF LIVER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERGAMMAGLOBULINAEMIA BENIGN MONOCLONAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LENTIGO MALIGNA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPOMA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOBULAR BREAST CARCINOMA IN SITU	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHANGIOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA IN SITU	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MELANOCYTIC NAEVUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONOCLONAL GAMMOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELODYSPLASTIC SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAEVUS HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURILEMMOMA BENIGN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL FIBROMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OVARIAN GERM CELL TERATOMA BENIGN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLARY THYROID CANCER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARATHYROID TUMOUR BENIGN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYOGENIC GRANULOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEBORRHOEIC KERATOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN PAPILLOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SQUAMOUS CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TUMOUR PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	1094	69,9	1601	87,9	1070	66,8	1,16		Algorithm converged.	0,99	1,34	0,031		Algorithm converged.	-0,001	0,064	1,05		Algorithm converged.	1,00	1,10	0,0595	0,6739	0,96		Algorithm converged.	0,91	1,00
		>= 65	219	12,3	161	73,5	221	12,1	151	68,3	1,29		Algorithm converged.	0,85	1,94	0,052		Algorithm converged.	-0,033	0,137	1,08		Algorithm converged.	0,95	1,21	0,2314		0,93		Algorithm converged.	0,82	1,05
	AGEUSIA	< 65	1564	87,7	14	0,9	1601	87,9	11	0,7	1,31		Algorithm converged.	0,59	2,88	0,002		Algorithm converged.	-0,004	0,008	1,30		Algorithm converged.	0,59	2,86	0,5098	-	0,77		Algorithm converged.	0,35	1,69
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	AKATHISIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLODYNIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMNESIA	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ANOSMIA	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHASIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATAXIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AUDITORY NERVE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BALANCE DISORDER	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BELL'S PALSY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRACHIAL PLEXOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURNING SENSATION	< 65	1564	87,7	9	0,6	1601	87,9	4	0,2	2,31		Algorithm converged.	0,71	7,52	0,003		Algorithm converged.	-0,001	0,008	2,30		Algorithm converged.	0,71	7,46	0,1643	-	0,43		Algorithm converged.	0,13	1,41

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CAROTID ARTERY STENOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARPAL TUNNEL SYNDROME	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBELLAR SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CEREBRAL ISCHAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013		1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74	
	CERVICAL RADICULOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICOBRACHIAL SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLONUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COGNITIVE DISORDER	< 65	1564	87,7	15	1,0	1601	87,9	14	0,9	1,10		Algorithm converged.	0,53	2,28	0,001		Algorithm converged.	-0,006	0,007	1,10		Algorithm converged.	0,53	2,26	0,8028	-	0,91		Algorithm converged.	0,44	1,88
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	COMPLEX REGIONAL PAIN SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COORDINATION ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEMENTIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEPRESSED LEVEL OF CONSCIOUSNESS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISTURBANCE IN ATTENTION	< 65	1564	87,7	19	1,2	1601	87,9	11	0,7	1,78		Algorithm converged.	0,84	3,75	0,005		Algorithm converged.	-0,001	0,012	1,77		Algorithm converged.	0,84	3,70	0,1308	-	0,57		Algorithm converged.	0,27	1,18
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	DIZZINESS	< 65	1564	87,7	183	11,7	1601	87,9	185	11,6	1,01		Algorithm converged.	0,82	1,26	0,001		Algorithm converged.	-0,021	0,024	1,01		Algorithm converged.	0,84	1,23	0,8984	0,3617	0,99		Algorithm converged.	0,81	1,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	32	14,6	221	12,1	25	11,3	1,34		Algorithm converged.	0,77	2,35	0,033		Algorithm converged.	-0,030	0,096	1,29		Algorithm converged.	0,79	2,11	0,3046		0,77		Algorithm converged.	0,47	1,26
	DIZZINESS POSTURAL	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSAESTHESIA	< 65	1564	87,7	20	1,3	1601	87,9	17	1,1	1,21		Algorithm converged.	0,63	2,31	0,002		Algorithm converged.	-0,005	0,010	1,20		Algorithm converged.	0,63	2,29	0,5708	-	0,83		Algorithm converged.	0,44	1,58
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	DYSARTHRIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	< 65	1564	87,7	261	16,7	1601	87,9	221	13,8	1,25		Algorithm converged.	1,03	1,52	0,029		Algorithm converged.	0,004	0,054	1,21		Algorithm converged.	1,02	1,43	0,0243	0,8461	0,83		Algorithm converged.	0,70	0,98
		>= 65	219	12,3	45	20,5	221	12,1	36	16,3	1,33		Algorithm converged.	0,82	2,16	0,043		Algorithm converged.	-0,030	0,115	1,26		Algorithm converged.	0,85	1,88	0,2509		0,79		Algorithm converged.	0,53	1,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSKINESIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTRIC SHOCK SENSATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESSENTIAL TREMOR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FACIAL NERVE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEBRILE CONVULSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FORMICATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHAGE INTRACRANIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAD DISCOMFORT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAD TITUBATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	< 65	1564	87,7	357	22,8	1601	87,9	390	24,4	0,92		Algorithm converged.	0,78	1,08	-0,015		Algorithm converged.	-0,045	0,014	0,94		Algorithm converged.	0,83	1,06	0,3099	0,2354	1,07		Algorithm converged.	0,94	1,21
		>= 65	219	12,3	41	18,7	221	12,1	34	15,4	1,27		Algorithm converged.	0,77	2,09	0,033		Algorithm converged.	-0,037	0,104	1,22		Algorithm converged.	0,80	1,84	0,3532		0,82		Algorithm converged.	0,54	1,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEMIANOPIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERAESTHESIA	< 65	1564	87,7	5	0,3	1601	87,9	9	0,6	0,57		Algorithm converged.	0,19	1,70	-0,002		Algorithm converged.	-0,007	0,002	0,57		Algorithm converged.	0,19	1,69	0,3106	-	1,76		Algorithm converged.	0,59	5,24
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERGEUSIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPATHIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSOMNIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTONIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOAESTHESIA	< 65	1564	87,7	62	4,0	1601	87,9	58	3,6	1,10		Algorithm converged.	0,76	1,58	0,003		Algorithm converged.	-0,010	0,017	1,09		Algorithm converged.	0,77	1,55	0,6152	-	0,91		Algorithm converged.	0,64	1,30
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83
	HYPOGEUSIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOSMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOTONIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERCOSTAL NEURALGIA	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LACUNAR INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LETHARGY	< 65	1564	87,7	18	1,2	1601	87,9	26	1,6	0,71		Algorithm converged.	0,39	1,29	-0,005		Algorithm converged.	-0,013	0,003	0,71		Algorithm converged.	0,39	1,29	0,2582	-	1,41		Algorithm converged.	0,78	2,56
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	LOSS OF CONSCIOUSNESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MEMORY IMPAIRMENT	< 65	1564	87,7	27	1,7	1601	87,9	22	1,4	1,26		Algorithm converged.	0,71	2,22	0,004		Algorithm converged.	-0,005	0,012	1,26		Algorithm converged.	0,72	2,20	0,4234	-	0,80		Algorithm converged.	0,46	1,39
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	MENTAL IMPAIRMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIGRAINE	< 65	1564	87,7	14	0,9	1601	87,9	7	0,4	2,06		Algorithm converged.	0,83	5,11	0,005		Algorithm converged.	-0,001	0,010	2,05		Algorithm converged.	0,83	5,06	0,1206	-	0,49		Algorithm converged.	0,20	1,21
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIGRAINE WITH AURA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MORTON'S NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTIONS INVOLUNTARY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE SPASTICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NERVE COMPRESSION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURALGIA	< 65	1564	87,7	17	1,1	1601	87,9	17	1,1	1,02		Algorithm converged.	0,52	2,01	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,52	2,00	0,9454	-	0,98		Algorithm converged.	0,50	1,91
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	< 65	1564	87,7	238	15,2	1601	87,9	228	14,2	1,08		Algorithm converged.	0,89	1,32	0,010		Algorithm converged.	-0,015	0,034	1,07		Algorithm converged.	0,90	1,26	0,4385	0,6968	0,94		Algorithm converged.	0,79	1,11
		>= 65	219	12,3	46	21,0	221	12,1	40	18,1	1,20		Algorithm converged.	0,75	1,93	0,029		Algorithm converged.	-0,045	0,103	1,16		Algorithm converged.	0,79	1,70	0,4430		0,86		Algorithm converged.	0,59	1,26
	NEUROTOXICITY	< 65	1564	87,7	34	2,2	1601	87,9	38	2,4	0,91		Algorithm converged.	0,57	1,46	-0,002		Algorithm converged.	-0,012	0,008	0,92		Algorithm converged.	0,58	1,45	0,7066	-	1,09		Algorithm converged.	0,69	1,73
		>= 65	219	12,3	5	2,3	221	12,1	2	0,9	2,56		Algorithm converged.	0,49	13,33	0,014		Algorithm converged.	-0,010	0,037	2,52		Algorithm converged.	0,49	12,87	0,2656		0,40		Algorithm converged.	0,08	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OCCIPITAL NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPHTHALMIC MIGRAINE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOSTATIC INTOLERANCE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PARAESTHESIA	< 65	1564	87,7	172	11,0	1601	87,9	159	9,9	1,12		Algorithm converged.	0,89	1,41	0,011		Algorithm converged.	-0,011	0,032	1,11		Algorithm converged.	0,90	1,36	0,3274	0,6333	0,90		Algorithm converged.	0,74	1,11
		>= 65	219	12,3	28	12,8	221	12,1	29	13,1	0,97		Algorithm converged.	0,56	1,69	-0,003		Algorithm converged.	-0,066	0,059	0,97		Algorithm converged.	0,60	1,58	0,9162		1,03		Algorithm converged.	0,63	1,67
	PAROSMIA	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4	1,71		Algorithm converged.	0,62	4,72	0,003		Algorithm converged.	-0,002	0,008	1,71		Algorithm converged.	0,62	4,68	0,2998	-	0,59		Algorithm converged.	0,21	1,61
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL MOTOR NEUROPATHY	< 65	1564	87,7	11	0,7	1601	87,9	12	0,7	0,94		Algorithm converged.	0,41	2,13	0,000		Algorithm converged.	-0,006	0,005	0,94		Algorithm converged.	0,42	2,12	0,8784	-	1,07		Algorithm converged.	0,47	2,41
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	PERIPHERAL PARALYSIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL SENSORY NEUROPATHY	< 65	1564	87,7	282	18,0	1601	87,9	282	17,6	1,03		Algorithm converged.	0,86	1,23	0,004		Algorithm converged.	-0,023	0,031	1,02		Algorithm converged.	0,88	1,19	0,7594	0,7648	0,98		Algorithm converged.	0,84	1,13
		>= 65	219	12,3	38	17,4	221	12,1	40	18,1	0,95		Algorithm converged.	0,58	1,55	-0,007		Algorithm converged.	-0,079	0,064	0,96		Algorithm converged.	0,64	1,43	0,8373		1,04		Algorithm converged.	0,70	1,56

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHANTOM LIMB SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POLYNEUROPATHY	< 65	1564	87,7	36	2,3	1601	87,9	34	2,1	1,09		Algorithm converged.	0,68	1,74	0,002		Algorithm converged.	-0,008	0,012	1,08		Algorithm converged.	0,68	1,72	0,7334	0,6925	0,92		Algorithm converged.	0,58	1,47
		>= 65	219	12,3	5	2,3	221	12,1	6	2,7	0,84		Algorithm converged.	0,25	2,78	-0,004		Algorithm converged.	-0,033	0,025	0,84		Algorithm converged.	0,26	2,71	0,7720		1,19		Algorithm converged.	0,37	3,84
	PRESYNCOPE	< 65	1564	87,7	12	0,8	1601	87,9	12	0,7	1,02		Algorithm converged.	0,46	2,29	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,46	2,27	0,9542	-	0,98		Algorithm converged.	0,44	2,17
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOGENIC SEIZURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOMOTOR HYPERACTIVITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYRAMIDAL TRACT SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESTLESS LEGS SYNDROME	< 65	1564	87,7	10	0,6	1601	87,9	4	0,2	2,57		Algorithm converged.	0,80	8,21	0,004		Algorithm converged.	-0,001	0,009	2,56		Algorithm converged.	0,80	8,14	0,1116	-	0,39		Algorithm converged.	0,12	1,24
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36
	SCIATICA	< 65	1564	87,7	9	0,6	1601	87,9	12	0,7	0,77		Algorithm converged.	0,32	1,82	-0,002		Algorithm converged.	-0,007	0,004	0,77		Algorithm converged.	0,32	1,82	0,5476	-	1,30		Algorithm converged.	0,55	3,08
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	SEIZURE	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SENSORY DISTURBANCE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SENSORY LOSS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SOMNOLENCE	< 65	1564	87,7	13	0,8	1601	87,9	10	0,6	1,33		Algorithm converged.	0,58	3,05	0,002		Algorithm converged.	-0,004	0,008	1,33		Algorithm converged.	0,59	3,03	0,4954	-	0,75		Algorithm converged.	0,33	1,71
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	< 65	1564	87,7	20	1,3	1601	87,9	19	1,2	1,08		Algorithm converged.	0,57	2,03	0,001		Algorithm converged.	-0,007	0,009	1,08		Algorithm converged.	0,58	2,01	0,8146	0,0258	0,93		Algorithm converged.	0,50	1,73
		>= 65	219	12,3	11	5,0	221	12,1	2	0,9	5,79		Algorithm converged.	1,27	26,44	0,041		Algorithm converged.	0,010	0,073	5,55		Algorithm converged.	1,24	24,75	0,0246		0,18		Algorithm converged.	0,04	0,80
	TASTE DISORDER	< 65	1564	87,7	126	8,1	1601	87,9	105	6,6	1,25		Algorithm converged.	0,95	1,63	0,015		Algorithm converged.	-0,003	0,033	1,23		Algorithm converged.	0,96	1,58	0,1060	0,9862	0,81		Algorithm converged.	0,63	1,04
		>= 65	219	12,3	23	10,5	221	12,1	19	8,6	1,25		Algorithm converged.	0,66	2,36	0,019		Algorithm converged.	-0,036	0,074	1,22		Algorithm converged.	0,69	2,18	0,4975		0,82		Algorithm converged.	0,46	1,46

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENSION HEADACHE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THALAMIC INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC NEUROPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSIENT ISCHAEMIC ATTACK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TREMOR	< 65	1564	87,7	7	0,4	1601	87,9	8	0,5	0,90		Algorithm converged.	0,32	2,47	-0,001		Algorithm converged.	-0,005	0,004	0,90		Algorithm converged.	0,33	2,46	0,8311	-	1,12		Algorithm converged.	0,41	3,07
		>= 65	219	12,3	4	1,8	221	12,1	1	0,5	4,09		Algorithm converged.	0,45	36,92	0,014		Algorithm converged.	-0,006	0,034	4,04		Algorithm converged.	0,45	35,83	0,2103		0,25		Algorithm converged.	0,03	2,20
	TRIGEMINAL NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE				NE	NE
	VASCULAR ENCEPHALOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VOCAL CORD PARESIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
PRODUCT ISSUE	-Total	< 65	1564	87,7	8	0,5	1601	87,9	7	0,4	1,17		Algorithm converged.	0,42	3,24	0,001		Algorithm converged.	-0,004	0,006	1,17		Algorithm converged.	0,43	3,22	0,7612	1,0000	0,85		Algorithm converged.	0,31	2,35
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE BREAKAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE CONNECTION ISSUE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE DEFECTIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE ISSUE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE MALFUNCTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DEVICE OCCLUSION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	THROMBOSIS IN DEVICE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	423	27,0	1601	87,9	407	25,4	1,09		Algorithm converged.	0,93	1,27	0,016		Algorithm converged.	-0,014	0,047	1,06		Algorithm converged.	0,95	1,20	0,2990	0,7364	0,94		Algorithm converged.	0,84	1,06
		>= 65	219	12,3	56	25,6	221	12,1	50	22,6	1,17		Algorithm converged.	0,76	1,82	0,029		Algorithm converged.	-0,050	0,109	1,13		Algorithm converged.	0,81	1,58	0,4704		0,88		Algorithm converged.	0,63	1,23
	ADJUSTMENT DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADJUSTMENT DISORDER WITH DEPRESSED MOOD	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AFFECT LABILITY	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	AFFECTIVE DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AGITATION	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AGORAPHOBIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANXIETY	< 65	1564	87,7	99	6,3	1601	87,9	68	4,2	1,52		Algorithm converged.	1,11	2,09	0,021		Algorithm converged.	0,005	0,036	1,49		Algorithm converged.	1,10	2,01	0,0093	0,5505	0,67		Algorithm converged.	0,50	0,91
		>= 65	219	12,3	10	4,6	221	12,1	9	4,1	1,13		Algorithm converged.	0,45	2,83	0,005		Algorithm converged.	-0,033	0,043	1,12		Algorithm converged.	0,46	2,71	0,7990		0,89		Algorithm converged.	0,37	2,15
	ANXIETY DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APATHY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONFUSIONAL STATE	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DELUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSED MOOD	< 65	1564	87,7	13	0,8	1601	87,9	11	0,7	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,005	0,007	1,21		Algorithm converged.	0,54	2,69	0,6408	-	0,83		Algorithm converged.	0,37	1,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEPRESSION	< 65	1564	87,7	75	4,8	1601	87,9	70	4,4	1,10		Algorithm converged.	0,79	1,54	0,004		Algorithm converged.	-0,010	0,019	1,10		Algorithm converged.	0,80	1,51	0,5693	0,6843	0,91		Algorithm converged.	0,66	1,25
		>= 65	219	12,3	7	3,2	221	12,1	8	3,6	0,88		Algorithm converged.	0,31	2,47	-0,004		Algorithm converged.	-0,038	0,030	0,88		Algorithm converged.	0,33	2,39	0,8067		1,13		Algorithm converged.	0,42	3,07
	DEPRESSIVE SYMPTOM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISORIENTATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMOTIONAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMOTIONAL DISTRESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENURESIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITO-PELVIC PAIN/PENETRATION DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HALLUCINATION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ILLUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	< 65	1564	87,7	252	16,1	1601	87,9	269	16,8	0,95		Algorithm converged.	0,79	1,15	-0,007		Algorithm converged.	-0,033	0,019	0,96		Algorithm converged.	0,82	1,12	0,6011	0,7361	1,04		Algorithm converged.	0,89	1,22
		>= 65	219	12,3	33	15,1	221	12,1	32	14,5	1,05		Algorithm converged.	0,62	1,77	0,006		Algorithm converged.	-0,060	0,072	1,04		Algorithm converged.	0,66	1,63	0,8618		0,96		Algorithm converged.	0,61	1,51
	IRRITABILITY	< 65	1564	87,7	8	0,5	1601	87,9	11	0,7	0,74		Algorithm converged.	0,30	1,85	-0,002		Algorithm converged.	-0,007	0,004	0,74		Algorithm converged.	0,30	1,85	0,5242	-	1,34		Algorithm converged.	0,54	3,33
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIBIDO DECREASED	< 65	1564	87,7	10	0,6	1601	87,9	9	0,6	1,14		Algorithm converged.	0,46	2,81	0,001		Algorithm converged.	-0,005	0,006	1,14		Algorithm converged.	0,46	2,79	0,7787	-	0,88		Algorithm converged.	0,36	2,16
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIBIDO DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOSS OF LIBIDO	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAJOR DEPRESSION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MANIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	< 65	1564	87,7	5	0,3	1601	87,9	2	0,1	2,56		Algorithm converged.	0,50	13,24	0,002		Algorithm converged.	-0,001	0,005	2,56		Algorithm converged.	0,50	13,17	0,2610	-	0,39		Algorithm converged.	0,08	2,01
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENTAL STATUS CHANGES	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIXED ANXIETY AND DEPRESSIVE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MOOD ALTERED	< 65	1564	87,7	12	0,8	1601	87,9	12	0,7	1,02		Algorithm converged.	0,46	2,29	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,46	2,27	0,9542	-	0,98		Algorithm converged.	0,44	2,17
		>= 65	219	12,3	6	2,7	221	12,1	1	0,5	6,20		Algorithm converged.	0,74	51,91	0,023		Algorithm converged.	0,000	0,046	6,05		Algorithm converged.	0,73	49,88	0,0942		0,17		Algorithm converged.	0,02	1,36
	MOOD SWINGS	< 65	1564	87,7	11	0,7	1601	87,9	11	0,7	1,02		Algorithm converged.	0,44	2,37	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,45	2,35	0,9561	-	0,98		Algorithm converged.	0,42	2,25
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NERVOUSNESS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHTMARE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOPHAGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORGANIC BRAIN SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANIC ATTACK	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARASOMNIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSISTENT DEPRESSIVE DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PERSONALITY CHANGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	POOR QUALITY SLEEP	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHIATRIC SYMPTOM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	REACTIVE PSYCHOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	RESTLESSNESS	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SELF ESTEEM DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SLEEP DISORDER	< 65	1564	87,7	19	1,2	1601	87,9	17	1,1	1,15		Algorithm converged.	0,59	2,21	0,002		Algorithm converged.	-0,006	0,009	1,14		Algorithm converged.	0,60	2,19	0,6851	-	0,87		Algorithm converged.	0,46	1,68
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	STRESS	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDE ATTEMPT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TEARFULNESS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THINKING ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VOMITING PSYCHOGENIC	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	116	7,4	1601	87,9	119	7,4	1,00		Algorithm converged.	0,76	1,30	0,000		Algorithm converged.	-0,018	0,018	1,00		Algorithm converged.	0,78	1,28	0,9863	0,8045	1,00		Algorithm converged.	0,78	1,28
		>= 65	219	12,3	22	10,0	221	12,1	24	10,9	0,92		Algorithm converged.	0,50	1,69	-0,008		Algorithm converged.	-0,065	0,049	0,93		Algorithm converged.	0,54	1,60	0,7803		1,08		Algorithm converged.	0,63	1,87
	ACUTE KIDNEY INJURY	< 65	1564	87,7	6	0,4	1601	87,9	2	0,1	3,08		Algorithm converged.	0,62	15,28	0,003		Algorithm converged.	-0,001	0,006	3,07		Algorithm converged.	0,62	15,19	0,1690	-	0,33		Algorithm converged.	0,07	1,61
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLADDER DISCOMFORT	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLADDER PROLAPSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	COSTOVERTEBRAL ANGLE TENDERNESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS HAEMORRHAGIC	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYSTITIS INTERSTITIAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS NONINFECTIVE	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSURIA	< 65	1564	87,7	45	2,9	1601	87,9	45	2,8	1,02		Algorithm converged.	0,67	1,56	0,001		Algorithm converged.	-0,011	0,012	1,02		Algorithm converged.	0,68	1,54	0,9104	0,6400	0,98		Algorithm converged.	0,65	1,47
		>= 65	219	12,3	8	3,7	221	12,1	10	4,5	0,80		Algorithm converged.	0,31	2,07	-0,009		Algorithm converged.	-0,046	0,028	0,81		Algorithm converged.	0,32	2,01	0,6450		1,24		Algorithm converged.	0,50	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATURIA	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTONIC BLADDER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCONTINENCE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	LEUKOCYTURIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICTURITION DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICTURITION URGENCY	< 65	1564	87,7	9	0,6	1601	87,9	4	0,2	2,31		Algorithm converged.	0,71	7,52	0,003		Algorithm converged.	-0,001	0,008	2,30		Algorithm converged.	0,71	7,46	0,1643	-	0,43		Algorithm converged.	0,13	1,41
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	NEPHROLITHIASIS	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NOCTURIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POLLAKIURIA	< 65	1564	87,7	19	1,2	1601	87,9	21	1,3	0,93		Algorithm converged.	0,50	1,73	-0,001		Algorithm converged.	-0,009	0,007	0,93		Algorithm converged.	0,50	1,72	0,8074	-	1,08		Algorithm converged.	0,58	2,00
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POLYURIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PROTEINURIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RENAL CYST	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL FAILURE	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL IMPAIRMENT	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRANGURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRESS URINARY INCONTINENCE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URETEROLITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URGE INCONTINENCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY HESITATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY INCONTINENCE	< 65	1564	87,7	5	0,3	1601	87,9	8	0,5	0,64		Algorithm converged.	0,21	1,96	-0,002		Algorithm converged.	-0,006	0,003	0,64		Algorithm converged.	0,21	1,95	0,4325	-	1,56		Algorithm converged.	0,51	4,77
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	URINARY RETENTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	URINARY TRACT INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT PAIN	< 65	1564	87,7	8	0,5	1601	87,9	3	0,2	2,74		Algorithm converged.	0,73	10,34	0,003		Algorithm converged.	-0,001	0,007	2,73		Algorithm converged.	0,73	10,27	0,1374	-	0,37		Algorithm converged.	0,10	1,38
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINE ODOUR ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROGENITAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	< 65	1564	87,7	296	18,9	1601	87,9	286	17,9	1,07		Algorithm converged.	0,90	1,28	0,011		Algorithm converged.	-0,016	0,038	1,06		Algorithm converged.	0,91	1,23	0,4407	0,8575	0,94		Algorithm converged.	0,82	1,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	26	11,9	221	12,1	26	11,8	1,01		Algorithm converged.	0,57	1,80	0,001		Algorithm converged.	-0,059	0,061	1,01		Algorithm converged.	0,61	1,68	0,9722		0,99		Algorithm converged.	0,59	1,65
	AMENORRHOEA	< 65	1564	87,7	31	2,0	1601	87,9	30	1,9	1,06		Algorithm converged.	0,64	1,76	0,001		Algorithm converged.	-0,009	0,011	1,06		Algorithm converged.	0,64	1,74	0,8247	-	0,95		Algorithm converged.	0,58	1,55
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATROPHIC VULVOVAGINITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BARTHOLIN'S CYST	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST ATROPHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CALCIFICATIONS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CYST	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST DISCHARGE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BREAST DISCOLOURATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST DISCOMFORT	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST ENGORGEMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ENLARGEMENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST INDURATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST INFLAMMATION	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST MASS	< 65	1564	87,7	8	0,5	1601	87,9	2	0,1	4,11		Algorithm converged.	0,87	19,39	0,004		Algorithm converged.	0,000	0,008	4,09		Algorithm converged.	0,87	19,25	0,0743	-	0,24		Algorithm converged.	0,05	1,15
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST OEDEMA	< 65	1564	87,7	18	1,2	1601	87,9	14	0,9	1,32		Algorithm converged.	0,65	2,66	0,003		Algorithm converged.	-0,004	0,010	1,32		Algorithm converged.	0,66	2,64	0,4385	-	0,76		Algorithm converged.	0,38	1,52
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	BREAST PAIN	< 65	1564	87,7	64	4,1	1601	87,9	67	4,2	0,98		Algorithm converged.	0,69	1,39	-0,001		Algorithm converged.	-0,015	0,013	0,98		Algorithm converged.	0,70	1,37	0,8957	0,9090	1,02		Algorithm converged.	0,73	1,43
		>= 65	219	12,3	12	5,5	221	12,1	13	5,9	0,93		Algorithm converged.	0,41	2,08	-0,004		Algorithm converged.	-0,047	0,039	0,93		Algorithm converged.	0,43	2,00	0,8552		1,07		Algorithm converged.	0,50	2,30
	BREAST SWELLING	< 65	1564	87,7	5	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST TENDERNESS	< 65	1564	87,7	2	0,1	1601	87,9	8	0,5	0,25		Algorithm converged.	0,05	1,20	-0,004		Algorithm converged.	-0,008	0,000	0,26		Algorithm converged.	0,05	1,20	0,0844	-	3,91		Algorithm converged.	0,83	18,37
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL POLYP	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSMENORRHOEA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPAREUNIA	< 65	1564	87,7	15	1,0	1601	87,9	13	0,8	1,18		Algorithm converged.	0,56	2,49	0,001		Algorithm converged.	-0,005	0,008	1,18		Algorithm converged.	0,56	2,47	0,6590	-	0,85		Algorithm converged.	0,40	1,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ECTROPION OF CERVIX	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENDOMETRIAL HYPERPLASIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOMETRIAL HYPERTROPHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENDOMETRIAL THICKENING	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOMETRIOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERECTILE DYSFUNCTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GALACTORRHOEA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL PROLAPSE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL RASH	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL TRACT INFLAMMATION	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL ULCERATION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAVY MENSTRUAL BLEEDING	< 65	1564	87,7	8	0,5	1601	87,9	4	0,2	2,05		Algorithm converged.	0,62	6,83	0,003		Algorithm converged.	-0,002	0,007	2,05		Algorithm converged.	0,62	6,79	0,2412	-	0,49		Algorithm converged.	0,15	1,62
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERMENSTRUAL BLEEDING	< 65	1564	87,7	7	0,4	1601	87,9	11	0,7	0,65		Algorithm converged.	0,25	1,68	-0,002		Algorithm converged.	-0,008	0,003	0,65		Algorithm converged.	0,25	1,68	0,3741	-	1,54		Algorithm converged.	0,60	3,95
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENOMETRORRHAGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENOPAUSAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENOPAUSAL SYMPTOMS	< 65	1564	87,7	6	0,4	1601	87,9	3	0,2	2,05		Algorithm converged.	0,51	8,22	0,002		Algorithm converged.	-0,002	0,006	2,05		Algorithm converged.	0,51	8,17	0,3103	-	0,49		Algorithm converged.	0,12	1,95

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients	Patients with Event	Patients	Patients with Event	Odds Ratio					Absolute Risk Difference							Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MENSTRUAL DISORDER	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MENSTRUATION IRREGULAR	< 65	1564	87,7	30	1,9	1601	87,9	37	2,3	0,83		Algorithm converged.	0,51	1,34	-0,004		Algorithm converged.	-0,014	0,006	0,83		Algorithm converged.	0,52	1,34	0,4434	-	1,20		Algorithm converged.	0,75	1,94
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NIPPLE EXUDATE BLOODY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	OLIGOMENORRHOEA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	OVARIAN CYST	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC CYST	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC DISCOMFORT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC FLOOR MUSCLE WEAKNESS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC PAIN	< 65	1564	87,7	3	0,2	1601	87,9	13	0,8	0,23		Algorithm converged.	0,07	0,83	-0,006		Algorithm converged.	-0,011	-0,001	0,24		Algorithm converged.	0,07	0,83	0,0241	-	4,23		Algorithm converged.	1,21	14,83
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERINEAL ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERINEAL PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERINEAL ULCERATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PREMATURE MENOPAUSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS GENITAL	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk (Interaction Test p-value (likelihood ratio)		Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)				Convergence Reason	95% Lower CL	95% Upper CL						
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE				
	REPRODUCTIVE TRACT DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE		-	NE		Algorithm converged.	NE	NE				
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE				

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RETRACTED NIPPLE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UTERINE HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE POLYP	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL CYST	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL DISCHARGE	< 65	1564	87,7	26	1,7	1601	87,9	21	1,3	1,27		Algorithm converged.	0,71	2,27	0,004		Algorithm converged.	-0,005	0,012	1,27		Algorithm converged.	0,72	2,24	0,4159	-	0,79		Algorithm converged.	0,45	1,40
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL HAEMORRHAGE	< 65	1564	87,7	13	0,8	1601	87,9	16	1,0	0,83		Algorithm converged.	0,40	1,73	-0,002		Algorithm converged.	-0,008	0,005	0,83		Algorithm converged.	0,40	1,72	0,6201	-	1,20		Algorithm converged.	0,58	2,49

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VAGINAL LESION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAL ULCERATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAR EROSION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276 86 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL BURNING SENSATION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DISCOMFORT	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL DRYNESS	< 65	1564	87,7	63	4,0	1601	87,9	59	3,7	1,10		Algorithm converged.	0,76	1,58	0,003		Algorithm converged.	-0,010	0,017	1,09		Algorithm converged.	0,77	1,55	0,6165	-	0,91		Algorithm converged.	0,65	1,30
		>= 65	219	12,3	2	0,9	221	12,1	5	2,3	0,40		Algorithm converged.	0,08	2,07	-0,013		Algorithm converged.	-0,037	0,010	0,40		Algorithm converged.	0,08	2,06	0,2751		2,48		Algorithm converged.	0,49	12,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL INFLAMMATION	< 65	1564	87,7	7	0,4	1601	87,9	7	0,4	1,02		Algorithm converged.	0,36	2,93	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,36	2,91	0,9650	-	0,98		Algorithm converged.	0,34	2,78
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	VULVOVAGINAL PAIN	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	VULVOVAGINAL PRURITUS	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL RASH	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	749	47,9	1601	87,9	699	43,7	1,19		Algorithm converged.	1,03	1,36	0,042		Algorithm converged.	0,008	0,077	1,10		Algorithm converged.	1,02	1,18	0,0170	1,0000	0,91		Algorithm converged.	0,84	0,98
		>= 65	219	12,3	100	45,7	221	12,1	92	41,6	1,18		Algorithm converged.	0,81	1,72	0,040		Algorithm converged.	-0,052	0,133	1,10		Algorithm converged.	0,89	1,36	0,3942		0,91		Algorithm converged.	0,74	1,13
	ACUTE RESPIRATORY DISTRESS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ALLERGIC SINUSITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APHONIA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APNOEA	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHMA	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATELECTASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHIAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIECTASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHOPNEUMOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	< 65	1564	87,7	2	0,1	1601	87,9	8	0,5	0,25		Algorithm converged.	0,05	1,20	-0,004		Algorithm converged.	-0,008	0,000	0,26		Algorithm converged.	0,05	1,20	0,0844	-	3,91		Algorithm converged.	0,83	18,37
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSTENOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARRH	< 65	1564	87,7	9	0,6	1601	87,9	7	0,4	1,32		Algorithm converged.	0,49	3,55	0,001		Algorithm converged.	-0,004	0,006	1,32		Algorithm converged.	0,49	3,53	0,5848	-	0,76		Algorithm converged.	0,28	2,04
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CHOKING SENSATION	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COUGH	< 65	1564	87,7	251	16,0	1601	87,9	257	16,1	1,00		Algorithm converged.	0,83	1,21	0,000		Algorithm converged.	-0,026	0,026	1,00		Algorithm converged.	0,85	1,17	0,9976	0,2753	1,00		Algorithm converged.	0,85	1,17
		>= 65	219	12,3	34	15,5	221	12,1	26	11,8	1,38		Algorithm converged.	0,80	2,39	0,038		Algorithm converged.	-0,026	0,102	1,32		Algorithm converged.	0,82	2,12	0,2526		0,76		Algorithm converged.	0,47	1,22

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY THROAT	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSAESTHESIA PHARYNX	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DYSPHONIA	< 65	1564	87,7	21	1,3	1601	87,9	12	0,7	1,80		Algorithm converged.	0,88	3,68	0,006		Algorithm converged.	-0,001	0,013	1,79		Algorithm converged.	0,88	3,63	0,1055	-	0,56		Algorithm converged.	0,28	1,13
		>= 65	219	12,3	4	1,8	221	12,1	5	2,3	0,80		Algorithm converged.	0,21	3,03	-0,004		Algorithm converged.	-0,031	0,022	0,81		Algorithm converged.	0,22	2,97	0,7472		1,24		Algorithm converged.	0,34	4,55
	DYSPNOEA	< 65	1564	87,7	167	10,7	1601	87,9	171	10,7	1,00		Algorithm converged.	0,80	1,25	0,000		Algorithm converged.	-0,022	0,021	1,00		Algorithm converged.	0,82	1,22	0,9978	0,4649	1,00		Algorithm converged.	0,82	1,22
		>= 65	219	12,3	27	12,3	221	12,1	33	14,9	0,80		Algorithm converged.	0,46	1,38	-0,026		Algorithm converged.	-0,090	0,038	0,83		Algorithm converged.	0,51	1,33	0,4273		1,21		Algorithm converged.	0,75	1,94
	DYSPNOEA EXERTIONAL	< 65	1564	87,7	20	1,3	1601	87,9	29	1,8	0,70		Algorithm converged.	0,40	1,25	-0,005		Algorithm converged.	-0,014	0,003	0,71		Algorithm converged.	0,40	1,24	0,2274	-	1,42		Algorithm converged.	0,80	2,49
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83
	EPISTAXIS	< 65	1564	87,7	264	16,9	1601	87,9	214	13,4	1,32		Algorithm converged.	1,08	1,60	0,035		Algorithm converged.	0,010	0,060	1,26		Algorithm converged.	1,07	1,49	0,0059	0,2550	0,79		Algorithm converged.	0,67	0,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	40	18,3	221	12,1	24	10,9	1,83		Algorithm converged.	1,06	3,16	0,074		Algorithm converged.	0,008	0,140	1,68		Algorithm converged.	1,05	2,69	0,0303		0,59		Algorithm converged.	0,37	0,95
	HAEMOPTYSIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HICCUPS	< 65	1564	87,7	4	0,3	1601	87,9	8	0,5	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,007	0,002	0,51		Algorithm converged.	0,15	1,70	0,2733	-	1,95		Algorithm converged.	0,59	6,48
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERVENTILATION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPOXIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTERSTITIAL LUNG DISEASE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGEAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL INFLAMMATION	< 65	1564	87,7	2	0,1	1601	87,9	7	0,4	0,29		Algorithm converged.	0,06	1,41	-0,003		Algorithm converged.	-0,007	0,001	0,29		Algorithm converged.	0,06	1,41	0,1248	-	3,42		Algorithm converged.	0,71	16,43
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL PAIN	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER RESPIRATORY TRACT CONGESTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LUNG DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG INFILTRATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL CONGESTION	< 65	1564	87,7	33	2,1	1601	87,9	48	3,0	0,70		Algorithm converged.	0,45	1,09	-0,009		Algorithm converged.	-0,020	0,002	0,70		Algorithm converged.	0,45	1,09	0,1157	-	1,42		Algorithm converged.	0,92	2,20
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL CRUSTING	< 65	1564	87,7	7	0,4	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,026	*	WARNING: The relative Hessian convergence criterion of 26.292068071 is greater than the limit of 0.0001. The convergence is questionable.	-0,026	0,078	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL DISCOMFORT	< 65	1564	87,7	11	0,7	1601	87,9	8	0,5	1,41		Algorithm converged.	0,57	3,52	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,49	0,4606	-	0,71		Algorithm converged.	0,29	1,76
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	NASAL DRYNESS	< 65	1564	87,7	37	2,4	1601	87,9	25	1,6	1,53		Algorithm converged.	0,92	2,55	0,008		Algorithm converged.	-0,002	0,018	1,52		Algorithm converged.	0,92	2,50	0,1052	-	0,66		Algorithm converged.	0,40	1,09
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	NASAL INFLAMMATION	< 65	1564	87,7	14	0,9	1601	87,9	12	0,7	1,20		Algorithm converged.	0,55	2,59	0,001		Algorithm converged.	-0,005	0,008	1,19		Algorithm converged.	0,55	2,57	0,6505	-	0,84		Algorithm converged.	0,39	1,80
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	NASAL MUCOSAL DISORDER	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL			Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL OBSTRUCTION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL OEDEMA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL POLYPS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL SEPTUM ULCERATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL TURBINATE HYPERTROPHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL ULCER	< 65	1564	87,7	10	0,6	1601	87,9	4	0,2	2,57		Algorithm converged.	0,80	8,21	0,004		Algorithm converged.	-0,001	0,009	2,56		Algorithm converged.	0,80	8,14	0,1116	-	0,39		Algorithm converged.	0,12	1,24
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OROPHARYNGEAL DISCOMFORT	< 65	1564	87,7	4	0,3	1601	87,9	6	0,4	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,005	0,003	0,68		Algorithm converged.	0,19	2,41	0,5533	-	1,47		Algorithm converged.	0,41	5,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	OROPHARYNGEAL PAIN	< 65	1564	87,7	155	9,9	1601	87,9	127	7,9	1,28		Algorithm converged.	1,00	1,63	0,020		Algorithm converged.	0,000	0,040	1,25		Algorithm converged.	1,00	1,56	0,0514	0,5453	0,80		Algorithm converged.	0,64	1,00
		>= 65	219	12,3	13	5,9	221	12,1	8	3,6	1,68		Algorithm converged.	0,68	4,14	0,023		Algorithm converged.	-0,017	0,063	1,64		Algorithm converged.	0,69	3,88	0,2600		0,61		Algorithm converged.	0,26	1,44
	OROPHARYNGEAL PLAQUE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOPNOEA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAINFUL RESPIRATION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARANASAL SINUS DISCOMFORT	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARANASAL SINUS HYPERSECRETION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGEAL ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	PHARYNGEAL INFLAMMATION	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGEAL SWELLING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL EFFUSION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	PLEURAL THICKENING	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PLEURITIC PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	< 65	1564	87,7	6	0,4	1601	87,9	5	0,3	1,23		Algorithm converged.	0,37	4,04	0,001		Algorithm converged.	-0,003	0,005	1,23		Algorithm converged.	0,38	4,02	0,7336	-	0,81		Algorithm converged.	0,25	2,66
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRODUCTIVE COUGH	< 65	1564	87,7	14	0,9	1601	87,9	15	0,9	0,96		Algorithm converged.	0,46	1,99	0,000		Algorithm converged.	-0,007	0,006	0,96		Algorithm converged.	0,46	1,97	0,9019	-	1,05		Algorithm converged.	0,51	2,16
		>= 65	219	12,3	5	2,3	221	12,1	2	0,9	2,56		Algorithm converged.	0,49	13,33	0,014		Algorithm converged.	-0,010	0,037	2,52		Algorithm converged.	0,49	12,87	0,2656		0,40		Algorithm converged.	0,08	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY CONGESTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PULMONARY HYPERTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PULMONARY PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RALES	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	REFLUX LARYNGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT CONGESTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RESPIRATORY TRACT IRRITATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RHINALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RHINITIS ALLERGIC	< 65	1564	87,7	25	1,6	1601	87,9	27	1,7	0,95		Algorithm converged.	0,55	1,64	-0,001		Algorithm converged.	-0,010	0,008	0,95		Algorithm converged.	0,55	1,63	0,8457	-	1,06		Algorithm converged.	0,62	1,81
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHINORRHOEA	< 65	1564	87,7	119	7,6	1601	87,9	77	4,8	1,63		Algorithm converged.	1,21	2,19	0,028		Algorithm converged.	0,011	0,045	1,58		Algorithm converged.	1,20	2,09	0,0012	0,8003	0,63		Algorithm converged.	0,48	0,83
		>= 65	219	12,3	23	10,5	221	12,1	16	7,2	1,50		Algorithm converged.	0,77	2,93	0,033		Algorithm converged.	-0,020	0,086	1,45		Algorithm converged.	0,79	2,67	0,2320		0,69		Algorithm converged.	0,37	1,27
	SINUS CONGESTION	< 65	1564	87,7	5	0,3	1601	87,9	2	0,1	2,56		Algorithm converged.	0,50	13,24	0,002		Algorithm converged.	-0,001	0,005	2,56		Algorithm converged.	0,50	13,17	0,2610	-	0,39		Algorithm converged.	0,08	2,01
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	SINUS DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SINUS PAIN	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SLEEP APNOEA SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SNEEZING	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPUTUM INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRIDOR	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYPNOEA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROAT IRRITATION	< 65	1564	87,7	4	0,3	1601	87,9	7	0,4	0,58		Algorithm converged.	0,17	2,00	-0,002		Algorithm converged.	-0,006	0,002	0,58		Algorithm converged.	0,17	1,99	0,3915	-	1,71		Algorithm converged.	0,50	5,83
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	THROAT TIGHTNESS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRACHEAL INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT CONGESTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER RESPIRATORY TRACT INFLAMMATION	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	UPPER RESPIRATORY TRACT IRRITATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER-AIRWAY COUGH SYNDROME	< 65	1564	87,7	17	1,1	1601	87,9	17	1,1	1,02		Algorithm converged.	0,52	2,01	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,52	2,00	0,9454	-	0,98		Algorithm converged.	0,50	1,91
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VOCAL CORD INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHEEZING	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	1386	88,6	1601	87,9	1351	84,4	1,44		Algorithm converged.	1,17	1,77	0,042		Algorithm converged.	0,019	0,066	1,05		Algorithm converged.	1,02	1,08	0,0005	0,2226	0,95		Algorithm converged.	0,93	0,98
		>= 65	219	12,3	180	82,2	221	12,1	183	82,8	0,96		Algorithm converged.	0,59	1,57	-0,006		Algorithm converged.	-0,077	0,065	0,99		Algorithm converged.	0,91	1,08	0,8655		1,01		Algorithm converged.	0,92	1,10
	ACNE	< 65	1564	87,7	22	1,4	1601	87,9	21	1,3	1,07		Algorithm converged.	0,59	1,96	0,001		Algorithm converged.	-0,007	0,009	1,07		Algorithm converged.	0,59	1,94	0,8175	-	0,93		Algorithm converged.	0,51	1,69
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACTINIC KERATOSIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA	< 65	1564	87,7	1075	68,7	1601	87,9	1093	68,3	1,02		Algorithm converged.	0,88	1,19	0,005		Algorithm converged.	-0,028	0,037	1,01		Algorithm converged.	0,96	1,06	0,7786	0,6623	0,99		Algorithm converged.	0,95	1,04
		>= 65	219	12,3	131	59,8	221	12,1	136	61,5	0,93		Algorithm converged.	0,63	1,36	-0,017		Algorithm converged.	-0,108	0,074	0,97		Algorithm converged.	0,84	1,13	0,7118		1,03		Algorithm converged.	0,89	1,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALOPECIA AREATA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA TOTALIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOEDEMA	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BLISTER	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4	1,71		Algorithm converged.	0,62	4,72	0,003		Algorithm converged.	-0,002	0,008	1,71		Algorithm converged.	0,62	4,68	0,2998	-	0,59		Algorithm converged.	0,21	1,61
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	BLOOD BLISTER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BUTTERFLY RASH	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLD SWEAT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMAL CYST	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS	< 65	1564	87,7	71	4,5	1601	87,9	58	3,6	1,27		Algorithm converged.	0,89	1,80	0,009		Algorithm converged.	-0,005	0,023	1,25		Algorithm converged.	0,89	1,76	0,1932	0,1465	0,80		Algorithm converged.	0,57	1,12
		>= 65	219	12,3	10	4,6	221	12,1	15	6,8	0,66		Algorithm converged.	0,29	1,50	-0,022		Algorithm converged.	-0,065	0,021	0,67		Algorithm converged.	0,31	1,46	0,3180		1,49		Algorithm converged.	0,68	3,24
	DERMATITIS ACNEIFORM	< 65	1564	87,7	56	3,6	1601	87,9	31	1,9	1,88		Algorithm converged.	1,21	2,93	0,016		Algorithm converged.	0,005	0,028	1,85		Algorithm converged.	1,20	2,85	0,0054	-	0,54		Algorithm converged.	0,35	0,83
		>= 65	219	12,3	6	2,7	221	12,1	2	0,9	3,08		Algorithm converged.	0,62	15,45	0,018		Algorithm converged.	-0,007	0,043	3,03		Algorithm converged.	0,62	14,84	0,1719		0,33		Algorithm converged.	0,07	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ALLERGIC	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4	1,71		Algorithm converged.	0,62	4,72	0,003		Algorithm converged.	-0,002	0,008	1,71		Algorithm converged.	0,62	4,68	0,2998	-	0,59		Algorithm converged.	0,21	1,61
		>= 65	219	12,3	0	0,0	221	12,1	4	1,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATITIS ATOPIC	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS BULLOUS	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS CONTACT	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	DERMATITIS DIAPER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG ERUPTION	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	< 65	1564	87,7	201	12,9	1601	87,9	172	10,7	1,23		Algorithm converged.	0,99	1,52	0,021		Algorithm converged.	-0,001	0,044	1,20		Algorithm converged.	0,99	1,45	0,0664	0,5181	0,84		Algorithm converged.	0,69	1,01
		>= 65	219	12,3	26	11,9	221	12,1	18	8,1	1,52		Algorithm converged.	0,81	2,86	0,037		Algorithm converged.	-0,019	0,093	1,46		Algorithm converged.	0,82	2,58	0,1960		0,69		Algorithm converged.	0,39	1,21
	DYSHIDROTIC ECZEMA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ECCHYMOSIS	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963694 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECZEMA	< 65	1564	87,7	30	1,9	1601	87,9	19	1,2	1,63		Algorithm converged.	0,91	2,91	0,007		Algorithm converged.	-0,001	0,016	1,62		Algorithm converged.	0,91	2,86	0,0990	-	0,62		Algorithm converged.	0,35	1,09
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	ECZEMA ASTEATOTIC	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPIDERMOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	< 65	1564	87,7	159	10,2	1601	87,9	150	9,4	1,09		Algorithm converged.	0,87	1,38	0,008		Algorithm converged.	-0,013	0,029	1,09		Algorithm converged.	0,88	1,34	0,4502	0,2521	0,92		Algorithm converged.	0,75	1,14
		>= 65	219	12,3	30	13,7	221	12,1	20	9,0	1,60		Algorithm converged.	0,88	2,91	0,046		Algorithm converged.	-0,013	0,106	1,51		Algorithm converged.	0,89	2,58	0,1281		0,66		Algorithm converged.	0,39	1,13
	ERYTHEMA MULTIFORME	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA NODOSUM	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ERYTHROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXCESSIVE GRANULATION TISSUE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXFOLIATIVE RASH	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HAIR GROWTH ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND DERMATITIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HANGNAIL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HIRSUTISM	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERHIDROSIS	< 65	1564	87,7	15	1,0	1601	87,9	12	0,7	1,28		Algorithm converged.	0,60	2,75	0,002		Algorithm converged.	-0,004	0,009	1,28		Algorithm converged.	0,60	2,72	0,5227	-	0,78		Algorithm converged.	0,37	1,66
		>= 65	219	12,3	0	0,0	221	12,1	4	1,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERKERATOSIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRICHOSIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	< 65	1564	87,7	9	0,6	1601	87,9	6	0,4	1,54		Algorithm converged.	0,55	4,33	0,002		Algorithm converged.	-0,003	0,007	1,54		Algorithm converged.	0,55	4,30	0,4148	-	0,65		Algorithm converged.	0,23	1,83
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	INTERTRIGO	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ITCHING SCAR	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LICHEN PLANUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVEDO RETICULARIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MACULE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MADAROSIS	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	MECHANICAL URTICARIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MILIARIA	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	NAIL BED BLEEDING	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL BED DISORDER	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED TENDERNESS	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	NAIL DISCOLOURATION	< 65	1564	87,7	118	7,5	1601	87,9	121	7,6	1,00		Algorithm converged.	0,77	1,30	0,000		Algorithm converged.	-0,019	0,018	1,00		Algorithm converged.	0,78	1,27	0,9889	0,7774	1,00		Algorithm converged.	0,78	1,28
		>= 65	219	12,3	18	8,2	221	12,1	20	9,0	0,90		Algorithm converged.	0,46	1,75	-0,008		Algorithm converged.	-0,061	0,044	0,91		Algorithm converged.	0,49	1,67	0,7566		1,10		Algorithm converged.	0,60	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL DISCOMFORT	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL DISORDER	< 65	1564	87,7	187	12,0	1601	87,9	183	11,4	1,05		Algorithm converged.	0,85	1,31	0,005		Algorithm converged.	-0,017	0,028	1,05		Algorithm converged.	0,86	1,27	0,6451	0,1044	0,96		Algorithm converged.	0,79	1,16
		>= 65	219	12,3	34	15,5	221	12,1	21	9,5	1,75		Algorithm converged.	0,98	3,12	0,060		Algorithm converged.	-0,001	0,122	1,63		Algorithm converged.	0,98	2,72	0,0596		0,61		Algorithm converged.	0,37	1,02
	NAIL DYSTROPHY	< 65	1564	87,7	11	0,7	1601	87,9	15	0,9	0,75		Algorithm converged.	0,34	1,64	-0,002		Algorithm converged.	-0,009	0,004	0,75		Algorithm converged.	0,35	1,63	0,4682	-	1,33		Algorithm converged.	0,61	2,89
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	NAIL GROWTH ABNORMAL	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL PIGMENTATION	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL RIDGING	< 65	1564	87,7	37	2,4	1601	87,9	32	2,0	1,19		Algorithm converged.	0,74	1,92	0,004		Algorithm converged.	-0,007	0,014	1,18		Algorithm converged.	0,74	1,89	0,4802	-	0,84		Algorithm converged.	0,53	1,35
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28
	NAIL TOXICITY	< 65	1564	87,7	46	2,9	1601	87,9	32	2,0	1,49		Algorithm converged.	0,94	2,35	0,009		Algorithm converged.	-0,001	0,020	1,47		Algorithm converged.	0,94	2,30	0,0894	0,7809	0,68		Algorithm converged.	0,44	1,06
		>= 65	219	12,3	7	3,2	221	12,1	4	1,8	1,79		Algorithm converged.	0,52	6,21	0,014		Algorithm converged.	-0,015	0,043	1,77		Algorithm converged.	0,52	5,95	0,3586		0,57		Algorithm converged.	0,17	1,91
	NEURODERMATITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHT SWEATS	< 65	1564	87,7	17	1,1	1601	87,9	22	1,4	0,79		Algorithm converged.	0,42	1,49	-0,003		Algorithm converged.	-0,011	0,005	0,79		Algorithm converged.	0,42	1,48	0,4651	-	1,26		Algorithm converged.	0,67	2,37
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NODULAR RASH	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ONYCHALGIA	< 65	1564	87,7	14	0,9	1601	87,9	9	0,6	1,60		Algorithm converged.	0,69	3,70	0,003		Algorithm converged.	-0,003	0,009	1,59		Algorithm converged.	0,69	3,67	0,2745	-	0,63		Algorithm converged.	0,27	1,45
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	ONYCHOCLASIS	< 65	1564	87,7	25	1,6	1601	87,9	23	1,4	1,11		Algorithm converged.	0,63	1,97	0,002		Algorithm converged.	-0,007	0,010	1,11		Algorithm converged.	0,63	1,95	0,7096	-	0,90		Algorithm converged.	0,51	1,58
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOLYSIS	< 65	1564	87,7	48	3,1	1601	87,9	58	3,6	0,84		Algorithm converged.	0,57	1,24	-0,006		Algorithm converged.	-0,018	0,007	0,85		Algorithm converged.	0,58	1,23	0,3873	0,2391	1,18		Algorithm converged.	0,81	1,72
		>= 65	219	12,3	6	2,7	221	12,1	13	5,9	0,45		Algorithm converged.	0,17	1,21	-0,031		Algorithm converged.	-0,069	0,006	0,47		Algorithm converged.	0,18	1,20	0,1146		2,15		Algorithm converged.	0,83	5,55
	ONYCHOMADESIS	< 65	1564	87,7	63	4,0	1601	87,9	56	3,5	1,16		Algorithm converged.	0,80	1,67	0,005		Algorithm converged.	-0,008	0,019	1,15		Algorithm converged.	0,81	1,64	0,4334	0,7251	0,87		Algorithm converged.	0,61	1,24
		>= 65	219	12,3	17	7,8	221	12,1	17	7,7	1,01		Algorithm converged.	0,50	2,03	0,001		Algorithm converged.	-0,049	0,051	1,01		Algorithm converged.	0,53	1,92	0,9780		0,99		Algorithm converged.	0,52	1,89
	ONYCHOMALACIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN OF SKIN	< 65	1564	87,7	17	1,1	1601	87,9	10	0,6	1,75		Algorithm converged.	0,80	3,83	0,005		Algorithm converged.	-0,002	0,011	1,74		Algorithm converged.	0,80	3,79	0,1628	-	0,57		Algorithm converged.	0,26	1,25
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86
	PALMAR ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	< 65	1564	87,7	140	9,0	1601	87,9	98	6,1	1,51		Algorithm converged.	1,15	1,97	0,028		Algorithm converged.	0,010	0,047	1,46		Algorithm converged.	1,14	1,88	0,0027	0,7443	0,68		Algorithm converged.	0,53	0,88
		>= 65	219	12,3	18	8,2	221	12,1	14	6,3	1,32		Algorithm converged.	0,64	2,73	0,019		Algorithm converged.	-0,030	0,067	1,30		Algorithm converged.	0,66	2,54	0,4482		0,77		Algorithm converged.	0,39	1,51
	PAPULE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PEAU D'ORANGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PETECHIAE	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PHOTOSENSITIVITY REACTION	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PIGMENTATION DISORDER	< 65	1564	87,7	7	0,4	1601	87,9	11	0,7	0,65		Algorithm converged.	0,25	1,68	-0,002		Algorithm converged.	-0,008	0,003	0,65		Algorithm converged.	0,25	1,68	0,3741	-	1,54		Algorithm converged.	0,60	3,95
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PITYRIASIS ROSEA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLANTAR ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURIGO	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	< 65	1564	87,7	231	14,8	1601	87,9	141	8,8	1,79		Algorithm converged.	1,44	2,24	0,060		Algorithm converged.	0,037	0,082	1,68		Algorithm converged.	1,38	2,04	<.0001	0,4864	0,60		Algorithm converged.	0,49	0,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	30	13,7	221	12,1	22	10,0	1,44		Algorithm converged.	0,80	2,58	0,037		Algorithm converged.	-0,023	0,098	1,38		Algorithm converged.	0,82	2,31	0,2266		0,73		Algorithm converged.	0,43	1,22
	PSORIASIS	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PURPURA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	RASH	< 65	1564	87,7	405	25,9	1601	87,9	333	20,8	1,33		Algorithm converged.	1,13	1,57	0,051		Algorithm converged.	0,022	0,080	1,24		Algorithm converged.	1,10	1,41	0,0007	0,1974	0,80		Algorithm converged.	0,71	0,91
		>= 65	219	12,3	56	25,6	221	12,1	35	15,8	1,83		Algorithm converged.	1,14	2,93	0,097		Algorithm converged.	0,022	0,173	1,61		Algorithm converged.	1,11	2,36	0,0132		0,62		Algorithm converged.	0,42	0,90
	RASH ERYTHEMATOUS	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH FOLLICULAR	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULAR	< 65	1564	87,7	10	0,6	1601	87,9	10	0,6	1,02		Algorithm converged.	0,42	2,47	0,000		Algorithm converged.	-0,005	0,006	1,02		Algorithm converged.	0,43	2,45	0,9582	-	0,98		Algorithm converged.	0,41	2,34
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	RASH MACULO-PAPULAR	< 65	1564	87,7	50	3,2	1601	87,9	39	2,4	1,32		Algorithm converged.	0,87	2,02	0,008		Algorithm converged.	-0,004	0,019	1,31		Algorithm converged.	0,87	1,98	0,1969	0,4499	0,76		Algorithm converged.	0,50	1,15
		>= 65	219	12,3	10	4,6	221	12,1	5	2,3	2,07		Algorithm converged.	0,69	6,15	0,023		Algorithm converged.	-0,011	0,057	2,02		Algorithm converged.	0,70	5,81	0,1929		0,50		Algorithm converged.	0,17	1,43
	RASH PAPULAR	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH PRURITIC	< 65	1564	87,7	11	0,7	1601	87,9	13	0,8	0,87		Algorithm converged.	0,39	1,94	-0,001		Algorithm converged.	-0,007	0,005	0,87		Algorithm converged.	0,39	1,93	0,7248	-	1,15		Algorithm converged.	0,52	2,57
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	RASH VESICULAR	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROSACEA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCAB	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SCAR PAIN	< 65	1564	87,7	14	0,9	1601	87,9	7	0,4	2,06		Algorithm converged.	0,83	5,11	0,005		Algorithm converged.	-0,001	0,010		2,05		Algorithm converged.	0,83	5,06	0,1206	-	0,49		Algorithm converged.	0,20	1,21
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEBORRHOEA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEBORRHOEIC DERMATITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SENSITIVE SKIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	SKIN ATROPHY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN BURNING SENSATION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN DEPIGMENTATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN DISCOLOURATION	< 65	1564	87,7	8	0,5	1601	87,9	10	0,6	0,82		Algorithm converged.	0,32	2,08	-0,001		Algorithm converged.	-0,006	0,004	0,82		Algorithm converged.	0,32	2,07	0,6728	-	1,22		Algorithm converged.	0,48	3,09
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	SKIN DISORDER	< 65	1564	87,7	13	0,8	1601	87,9	11	0,7	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,005	0,007	1,21		Algorithm converged.	0,54	2,69	0,6408	-	0,83		Algorithm converged.	0,37	1,84
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	SKIN EROSION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN EXFOLIATION	< 65	1564	87,7	27	1,7	1601	87,9	24	1,5	1,15		Algorithm converged.	0,66	2,01	0,002		Algorithm converged.	-0,007	0,011	1,15		Algorithm converged.	0,67	1,99	0,6120	-	0,87		Algorithm converged.	0,50	1,50
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83
	SKIN FISSURES	< 65	1564	87,7	24	1,5	1601	87,9	20	1,2	1,23		Algorithm converged.	0,68	2,24	0,003		Algorithm converged.	-0,005	0,011	1,23		Algorithm converged.	0,68	2,21	0,4939	-	0,81		Algorithm converged.	0,45	1,47
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	SKIN HYPERPIGMENTATION	< 65	1564	87,7	74	4,7	1601	87,9	66	4,1	1,16		Algorithm converged.	0,82	1,62	0,006		Algorithm converged.	-0,008	0,020	1,15		Algorithm converged.	0,83	1,59	0,4052	-	0,87		Algorithm converged.	0,63	1,21
		>= 65	219	12,3	5	2,3	221	12,1	3	1,4	1,70		Algorithm converged.	0,40	7,19	0,009		Algorithm converged.	-0,016	0,034	1,68		Algorithm converged.	0,41	6,95	0,4727		0,59		Algorithm converged.	0,14	2,46

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN HYPERTROPHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN HYPOPIGMENTATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN INDURATION	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963577 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN IRRITATION	< 65	1564	87,7	12	0,8	1601	87,9	8	0,5	1,54		Algorithm converged.	0,63	3,78	0,003		Algorithm converged.	-0,003	0,008	1,54		Algorithm converged.	0,63	3,75	0,3460	-	0,65		Algorithm converged.	0,27	1,59
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	< 65	1564	87,7	12	0,8	1601	87,9	6	0,4	2,06		Algorithm converged.	0,77	5,49	0,004		Algorithm converged.	-0,001	0,009	2,05		Algorithm converged.	0,77	5,44	0,1508	-	0,49		Algorithm converged.	0,18	1,30
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	SKIN MASS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN ODOUR ABNORMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN PLAQUE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN REACTION	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN SWELLING	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TIGHTNESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TOXICITY	< 65	1564	87,7	17	1,1	1601	87,9	8	0,5	2,19		Algorithm converged.	0,94	5,09	0,006		Algorithm converged.	0,000	0,012	2,18		Algorithm converged.	0,94	5,03	0,0689	-	0,46		Algorithm converged.	0,20	1,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18
	SKIN ULCER	< 65	1564	87,7	13	0,8	1601	87,9	9	0,6	1,48		Algorithm converged.	0,63	3,48	0,003		Algorithm converged.	-0,003	0,008	1,48		Algorithm converged.	0,63	3,45	0,3655	-	0,68		Algorithm converged.	0,29	1,58
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN WRINKLING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPIDER NAEVUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TELANGIECTASIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOXIC SKIN ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	UMBILICAL ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URTICARIA	< 65	1564	87,7	26	1,7	1601	87,9	25	1,6	1,07		Algorithm converged.	0,61	1,85	0,001		Algorithm converged.	-0,008	0,010	1,06		Algorithm converged.	0,62	1,84	0,8217	-	0,94		Algorithm converged.	0,54	1,62
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	URTICARIA CONTACT	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URTICARIA PAPULAR	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	XERODERMA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SOCIAL CIRCUMSTANCE	-Total	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INADEQUATE DIET	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENOPAUSE	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	< 65	1564	87,7	7	0,4	1601	87,9	9	0,6	0,80		Algorithm converged.	0,30	2,14	-0,001		Algorithm converged.	-0,006	0,004	0,80		Algorithm converged.	0,30	2,13	0,6502	-	1,26		Algorithm converged.	0,47	3,36
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	ASTRINGENT THERAPY	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST RECONSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST TUMOUR EXCISION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CENTRAL VENOUS CATHETER REMOVAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CENTRAL VENOUS CATHETERISATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DENTAL CARE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HOSPITALISATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS OPERATION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH RESTORATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	< 65	1564	87,7	562	35,9	1601	87,9	607	37,9	0,92		Algorithm converged.	0,79	1,06	-0,020		Algorithm converged.	-0,053	0,014	0,95		Algorithm converged.	0,87	1,04	0,2487	0,7471	1,06		Algorithm converged.	0,96	1,16
		>= 65	219	12,3	68	31,1	221	12,1	69	31,2	0,99		Algorithm converged.	0,66	1,49	-0,002		Algorithm converged.	-0,088	0,085	0,99		Algorithm converged.	0,75	1,31	0,9690		1,01		Algorithm converged.	0,76	1,33

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGIOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGIOSCLEROSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AORTIC DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTERIOSCLEROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE FLUCTUATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOODY DISCHARGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CIRCULATORY COLLAPSE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEEP VEIN THROMBOSIS	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY GANGRENE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	< 65	1564	87,7	11	0,7	1601	87,9	2	0,1	5,66		Algorithm converged.	1,25	25,59	0,006		Algorithm converged.	0,001	0,010	5,63		Algorithm converged.	1,25	25,36	0,0244	-	0,18		Algorithm converged.	0,04	0,80
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	EMBOLISM VENOUS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FLUSHING	< 65	1564	87,7	55	3,5	1601	87,9	54	3,4	1,04		Algorithm converged.	0,71	1,53	0,001		Algorithm converged.	-0,011	0,014	1,04		Algorithm converged.	0,72	1,51	0,8246	-	0,96		Algorithm converged.	0,66	1,39
		>= 65	219	12,3	4	1,8	221	12,1	5	2,3	0,80		Algorithm converged.	0,21	3,03	-0,004		Algorithm converged.	-0,031	0,022	0,81		Algorithm converged.	0,22	2,97	0,7472		1,24		Algorithm converged.	0,34	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HOT FLUSH	< 65	1564	87,7	320	20,5	1601	87,9	336	21,0	0,97		Algorithm converged.	0,82	1,15	-0,005		Algorithm converged.	-0,034	0,023	0,97		Algorithm converged.	0,85	1,12	0,7149	0,5173	1,03		Algorithm converged.	0,90	1,18
		>= 65	219	12,3	13	5,9	221	12,1	17	7,7	0,76		Algorithm converged.	0,36	1,60	-0,018		Algorithm converged.	-0,065	0,029	0,77		Algorithm converged.	0,38	1,55	0,4665		1,30		Algorithm converged.	0,65	2,60
	HYPERAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERTENSION	< 65	1564	87,7	64	4,1	1601	87,9	82	5,1	0,79		Algorithm converged.	0,57	1,10	-0,010		Algorithm converged.	-0,025	0,004	0,80		Algorithm converged.	0,58	1,10	0,1684	0,6874	1,25		Algorithm converged.	0,91	1,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	10	4,6	221	12,1	15	6,8	0,66		Algorithm converged.	0,29	1,50	-0,022		Algorithm converged.	-0,065	0,021	0,67		Algorithm converged.	0,31	1,46	0,3180		1,49		Algorithm converged.	0,68	3,24
	HYPERTENSIVE CRISIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOTENSION	< 65	1564	87,7	30	1,9	1601	87,9	24	1,5	1,29		Algorithm converged.	0,75	2,21	0,004		Algorithm converged.	-0,005	0,013	1,28		Algorithm converged.	0,75	2,18	0,3639	0,6327	0,78		Algorithm converged.	0,46	1,33
		>= 65	219	12,3	10	4,6	221	12,1	6	2,7	1,71		Algorithm converged.	0,61	4,80	0,019		Algorithm converged.	-0,016	0,053	1,68		Algorithm converged.	0,62	4,55	0,3056		0,59		Algorithm converged.	0,22	1,61
	INFERIOR VENA CAVA DILATATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERNAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	JUGULAR VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LYMPHOCELE	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LYMPHOEDEMA	< 65	1564	87,7	111	7,1	1601	87,9	134	8,4	0,84		Algorithm converged.	0,64	1,09	-0,013		Algorithm converged.	-0,031	0,006	0,85		Algorithm converged.	0,67	1,08	0,1811	0,3936	1,18		Algorithm converged.	0,93	1,50
		>= 65	219	12,3	13	5,9	221	12,1	21	9,5	0,60		Algorithm converged.	0,29	1,23	-0,036		Algorithm converged.	-0,085	0,014	0,62		Algorithm converged.	0,32	1,22	0,1662		1,60		Algorithm converged.	0,82	3,12
	LYMPHORRHOEA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOSTASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORTHOSTATIC HYPOTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	PALLOR	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL COLDNESS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL VASCULAR DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL VENOUS DISEASE	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	PHLEBITIS	< 65	1564	87,7	27	1,7	1601	87,9	33	2,1	0,83		Algorithm converged.	0,50	1,39	-0,003		Algorithm converged.	-0,013	0,006	0,84		Algorithm converged.	0,51	1,39	0,4904	-	1,19		Algorithm converged.	0,72	1,98
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHLEBITIS SUPERFICIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PREHYPERTENSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	SUPERFICIAL VEIN THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	6	0,4	0,17		Algorithm converged.	0,02	1,41	-0,003		Algorithm converged.	-0,006	0,000	0,17		Algorithm converged.	0,02	1,42	0,1014	-	5,86		Algorithm converged.	0,71	48,63
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPERIOR VENA CAVA OCCLUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPERIOR VENA CAVA SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	< 65	1564	87,7	6	0,4	1601	87,9	7	0,4	0,88		Algorithm converged.	0,29	2,62	-0,001		Algorithm converged.	-0,005	0,004	0,88		Algorithm converged.	0,30	2,60	0,8138	-	1,14		Algorithm converged.	0,38	3,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	THROMBOSED VARICOSE VEIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THROMBOSIS	< 65	1564	87,7	5	0,3	1601	87,9	13	0,8	0,39		Algorithm converged.	0,14	1,10	-0,005		Algorithm converged.	-0,010	0,000	0,39		Algorithm converged.	0,14	1,10	0,0758	-	2,54		Algorithm converged.	0,91	7,11
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	VARICOSE VEIN	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VASCULAR PAIN	< 65	1564	87,7	11	0,7	1601	87,9	8	0,5	1,41		Algorithm converged.	0,57	3,52	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,49	0,4606	-	0,71		Algorithm converged.	0,29	1,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VASCULAR RUPTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VASCULITIS	< 65	1564	87,7	15	1,0	1601	87,9	14	0,9	1,10		Algorithm converged.	0,53	2,28	0,001		Algorithm converged.	-0,006	0,007	1,10		Algorithm converged.	0,53	2,26	0,8028	-	0,91		Algorithm converged.	0,44	1,88
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASODILATATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VEIN DISCOLOURATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS LIMB	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_ANYAE_S1.xls
05MAY2022 13:13

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	151	57,6	252	13,8	136	54,0	1,16		Algorithm converged.	0,82	1,64	0,037		Algorithm converged.	-0,049	0,122	1,07		Algorithm converged.	0,92	1,25	0,4036	0,8544	0,94		Algorithm converged.	0,80	1,09
		Western Europe	814	45,7	395	48,5	824	45,2	373	45,3	1,14		Algorithm converged.	0,94	1,38	0,033		Algorithm converged.	-0,016	0,081	1,07		Algorithm converged.	0,97	1,19	0,1866		0,93		Algorithm converged.	0,84	1,03
		Asia Pacific	482	27,0	279	57,9	517	28,4	262	50,7	1,34		Algorithm converged.	1,04	1,72	0,072		Algorithm converged.	0,010	0,134	1,14		Algorithm converged.	1,02	1,28	0,0224		0,88		Algorithm converged.	0,78	0,98
		Latin America	42	2,4	28	66,7	45	2,5	26	57,8	1,46		Algorithm converged.	0,61	3,50	0,089		Algorithm converged.	-0,114	0,292	1,15		Algorithm converged.	0,83	1,60	0,3937		0,87		Algorithm converged.	0,62	1,20
		Other	183	10,3	89	48,6	184	10,1	88	47,8	1,03		Algorithm converged.	0,69	1,56	0,008		Algorithm converged.	-0,094	0,110	1,02		Algorithm converged.	0,82	1,26	0,8769		0,98		Algorithm converged.	0,80	1,22
	AGRANULOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	ANAEMIA	USA/Canada	262	14,7	106	40,5	252	13,8	92	36,5	1,18		Algorithm converged.	0,83	1,69	0,040		Algorithm converged.	-0,045	0,124	1,11		Algorithm converged.	0,89	1,38	0,3585	0,4055	0,90		Algorithm converged.	0,72	1,12
		Western Europe	814	45,7	194	23,8	824	45,2	173	21,0	1,18		Algorithm converged.	0,93	1,49	0,028		Algorithm converged.	-0,012	0,069	1,14		Algorithm converged.	0,95	1,36	0,1689		0,88		Algorithm converged.	0,74	1,06
		Asia Pacific	482	27,0	151	31,3	517	28,4	115	22,2	1,59		Algorithm converged.	1,20	2,12	0,091		Algorithm converged.	0,036	0,146	1,41		Algorithm converged.	1,14	1,73	0,0013		0,71		Algorithm converged.	0,58	0,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	15	35,7	45	2,5	15	33,3	1,11		Algorithm converged.	0,46	2,69	0,024		Algorithm converged.	-0,176	0,224	1,07		Algorithm converged.	0,60	1,91	0,8154		0,93		Algorithm converged.	0,52	1,67
		Other	183	10,3	38	20,8	184	10,1	38	20,7	1,01		Algorithm converged.	0,61	1,67	0,001		Algorithm converged.	-0,082	0,084	1,01		Algorithm converged.	0,67	1,50	0,9787		0,99		Algorithm converged.	0,67	1,48
	ANAEMIA MACROCYTIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BONE MARROW FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DISSEMINATED INTRAVASCULAR COAGULATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EOSINOPHILIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHROPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	21	8,0	252	13,8	23	9,1	0,87		Algorithm converged.	0,47	1,61	-0,011		Algorithm converged.	-0,060	0,037	0,88		Algorithm converged.	0,50	1,55	0,6527	-	1,14		Algorithm converged.	0,65	2,00
		Western Europe	814	45,7	97	11,9	824	45,2	100	12,1	0,98		Algorithm converged.	0,73	1,32	-0,002		Algorithm converged.	-0,034	0,029	0,98		Algorithm converged.	0,76	1,28	0,8914		1,02		Algorithm converged.	0,78	1,32
		Asia Pacific	482	27,0	74	15,4	517	28,4	56	10,8	1,49		Algorithm converged.	1,03	2,17	0,045		Algorithm converged.	0,003	0,087	1,42		Algorithm converged.	1,02	1,96	0,0350		0,71		Algorithm converged.	0,51	0,98
		Latin America	42	2,4	5	11,9	45	2,5	3	6,7	1,89		Algorithm converged.	0,42	8,46	0,052		Algorithm converged.	-0,070	0,174	1,79		Algorithm converged.	0,45	7,01	0,4062		0,56		Algorithm converged.	0,14	2,20
		Other	183	10,3	15	8,2	184	10,1	8	4,3	1,96		Algorithm converged.	0,81	4,75	0,038		Algorithm converged.	-0,011	0,088	1,89		Algorithm converged.	0,82	4,34	0,1359		0,53		Algorithm converged.	0,23	1,22

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRANULOCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	14	2,9	517	28,4	17	3,3	0,88		Algorithm converged.	0,43	1,80	-0,004		Algorithm converged.	-0,025	0,018		0,88		Algorithm converged.	0,44	1,77	0,7270		1,13		Algorithm converged.	0,56	2,27
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMATOTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOGLOBINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPERLEUKOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779			1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INCREASED TENDENCY TO BRUISE	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	IRON DEFICIENCY ANAEMIA	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LEUKOCYTOSIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	3	0,6	517	28,4	3	0,6	1,07		Algorithm converged.	0,22	5,34	0,000		Algorithm converged.	-0,009	0,010	1,07		Algorithm converged.	0,22	5,29	0,9314		0,93		Algorithm converged.	0,19	4,60	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	LEUKOPENIA	USA/Canada	262	14,7	13	5,0	252	13,8	9	3,6	1,41		Algorithm converged.	0,59	3,36	0,014		Algorithm converged.	-0,021	0,049	1,39		Algorithm converged.	0,60	3,19	0,4387	0,7305	0,72		Algorithm converged.	0,31	1,65	
		Western Europe	814	45,7	55	6,8	824	45,2	70	8,5	0,78		Algorithm converged.	0,54	1,13	-0,017		Algorithm converged.	-0,043	0,008	0,80		Algorithm converged.	0,57	1,12	0,1864		1,26		Algorithm converged.	0,90	1,77	
		Asia Pacific	482	27,0	63	13,1	517	28,4	75	14,5	0,89		Algorithm converged.	0,62	1,27	-0,014		Algorithm converged.	-0,057	0,028	0,90		Algorithm converged.	0,66	1,23	0,5113		1,11		Algorithm converged.	0,81	1,51	
		Latin America	42	2,4	6	14,3	45	2,5	6	13,3	1,08		Algorithm converged.	0,32	3,67	0,010		Algorithm converged.	-0,136	0,155	1,07		Algorithm converged.	0,37	3,06	0,8976		0,93		Algorithm converged.	0,33	2,67	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	30	16,4	184	10,1	29	15,8	1,05		Algorithm converged.	0,60	1,83	0,006		Algorithm converged.	-0,069	0,081		1,04		Algorithm converged.	0,65	1,66	0,8690		0,96		Algorithm converged.	0,60	1,53
	LYMPH NODE PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHADENITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHADENOPATHY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	LYMPHOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOID TISSUE HYPERPLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOPENIA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010	1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICROCYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICROCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	8	1,7	517	28,4	12	2,3	0,71		Algorithm converged.	0,29	1,75	-0,007		Algorithm converged.	-0,024	0,011		0,72		Algorithm converged.	0,29	1,73	0,4581		1,40		Algorithm converged.	0,58	3,39
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	USA/Canada	262	14,7	73	27,9	252	13,8	58	23,0	1,29		Algorithm converged.	0,87	1,92	0,048		Algorithm converged.	-0,027	0,124		1,21		Algorithm converged.	0,90	1,63	0,2092	0,9454	0,83		Algorithm converged.	0,61	1,11
		Western Europe	814	45,7	186	22,9	824	45,2	176	21,4	1,09		Algorithm converged.	0,86	1,38	0,015		Algorithm converged.	-0,025	0,055		1,07		Algorithm converged.	0,89	1,28	0,4673		0,93		Algorithm converged.	0,78	1,12
		Asia Pacific	482	27,0	137	28,4	517	28,4	135	26,1	1,12		Algorithm converged.	0,85	1,48	0,023		Algorithm converged.	-0,032	0,078		1,09		Algorithm converged.	0,89	1,33	0,4123		0,92		Algorithm converged.	0,75	1,13
		Latin America	42	2,4	17	40,5	45	2,5	16	35,6	1,23		Algorithm converged.	0,52	2,93	0,049		Algorithm converged.	-0,155	0,253		1,14		Algorithm converged.	0,66	1,95	0,6367		0,88		Algorithm converged.	0,51	1,50
		Other	183	10,3	55	30,1	184	10,1	46	25,0	1,29		Algorithm converged.	0,81	2,04	0,051		Algorithm converged.	-0,041	0,142		1,20		Algorithm converged.	0,86	1,68	0,2797		0,83		Algorithm converged.	0,60	1,16
	NEUTROPHILIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NORMOCHROMIC NORMOCYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCYTOPENIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	USA/Canada	262	14,7	30	11,5	252	13,8	28	11,1	1,03		Algorithm converged.	0,60	1,79	0,003		Algorithm converged.	-0,051	0,058	1,03		Algorithm converged.	0,63	1,67	0,9033	-	0,97		Algorithm converged.	0,60	1,58
		Western Europe	814	45,7	20	2,5	824	45,2	19	2,3	1,07		Algorithm converged.	0,57	2,01	0,002		Algorithm converged.	-0,013	0,016	1,07		Algorithm converged.	0,57	1,98	0,8410		0,94		Algorithm converged.	0,50	1,75
		Asia Pacific	482	27,0	18	3,7	517	28,4	11	2,1	1,78		Algorithm converged.	0,83	3,82	0,016		Algorithm converged.	-0,005	0,037	1,76		Algorithm converged.	0,84	3,68	0,1361		0,57		Algorithm converged.	0,27	1,19
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138	3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88
		Other	183	10,3	4	2,2	184	10,1	8	4,3	0,49		Algorithm converged.	0,15	1,66	-0,022		Algorithm converged.	-0,058	0,015	0,50		Algorithm converged.	0,15	1,64	0,2544		1,99		Algorithm converged.	0,61	6,49
	THROMBOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002169 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	36	13,7	252	13,8	39	15,5	0,87		Algorithm converged.	0,53	1,42	-0,017		Algorithm converged.	-0,078	0,044	0,89		Algorithm converged.	0,58	1,35	0,5776	-	1,13		Algorithm converged.	0,74	1,71
		Western Europe	814	45,7	101	12,4	824	45,2	87	10,6	1,20		Algorithm converged.	0,88	1,63	0,018		Algorithm converged.	-0,012	0,049	1,18		Algorithm converged.	0,90	1,54	0,2410		0,85		Algorithm converged.	0,65	1,11
		Asia Pacific	482	27,0	48	10,0	517	28,4	50	9,7	1,03		Algorithm converged.	0,68	1,57	0,003		Algorithm converged.	-0,034	0,040	1,03		Algorithm converged.	0,71	1,50	0,8787		0,97		Algorithm converged.	0,67	1,41
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103	2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	21	11,5	184	10,1	21	11,4	1,01		Algorithm converged.	0,53	1,91	0,001		Algorithm converged.	-0,065	0,066	1,01		Algorithm converged.	0,57	1,78	0,9850		0,99		Algorithm converged.	0,56	1,76
	ACUTE CORONARY SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	ANGINA PECTORIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662			1,48		Algorithm converged.	0,25	8,84	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	3	1,6	184	10,1	2	1,1	1,52		Algorithm converged.	0,25	9,18	0,006		Algorithm converged.	-0,018	0,029		1,51		Algorithm converged.	0,25	8,92	0,6505			0,66		Algorithm converged.	0,11	3,92	
	AORTIC VALVE INCOMPETENCE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AORTIC VALVE SCLEROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ARRHYTHMIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006	0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARTERIOSCLEROSIS CORONARY ARTERY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL FIBRILLATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	ATRIAL TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BIFASCICULAR BLOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRADYCARDIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUNDLE BRANCH BLOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BUNDLE BRANCH BLOCK LEFT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUNDLE BRANCH BLOCK RIGHT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	1	0,1	5,09		Algorithm converged.	0,59	43,63	0,005		Algorithm converged.	-0,001	0,011	5,06		Algorithm converged.	0,59	43,23	0,1384		0,20		Algorithm converged.	0,02	1,69
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	15	1,8	824	45,2	9	1,1	1,70		Algorithm converged.	0,74	3,91	0,008		Algorithm converged.	-0,004	0,019	1,69		Algorithm converged.	0,74	3,83	0,2116		0,59		Algorithm converged.	0,26	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE CONGESTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	CARDIOVASCULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIOVASCULAR INSUFFICIENCY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CONDUCTION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIASTOLIC DYSFUNCTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	EXTRASYSTOLES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEART VALVE INCOMPETENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE HEART DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEFT VENTRICULAR DILATATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LEFT VENTRICULAR DYSFUNCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LEFT VENTRICULAR HYPERTROPHY	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	METABOLIC CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	3	1,6	0,33		Algorithm converged.	0,03	3,22	-0,011		Algorithm converged.	-0,032	0,010	0,34		Algorithm converged.	0,04	3,19	0,3418		2,98		Algorithm converged.	0,31	28,42
	MITRAL VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MITRAL VALVE INCOMPETENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE PROLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	NODAL RHYTHM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALPITATIONS	USA/Canada	262	14,7	14	5,3	252	13,8	23	9,1	0,56		Algorithm converged.	0,28	1,12	-0,038		Algorithm converged.	-0,083	0,007	0,59		Algorithm converged.	0,31	1,11	0,1019	-	1,71		Algorithm converged.	0,90	3,24
		Western Europe	814	45,7	34	4,2	824	45,2	32	3,9	1,08		Algorithm converged.	0,66	1,77	0,003		Algorithm converged.	-0,016	0,022	1,08		Algorithm converged.	0,67	1,73	0,7628		0,93		Algorithm converged.	0,58	1,49
		Asia Pacific	482	27,0	26	5,4	517	28,4	20	3,9	1,42		Algorithm converged.	0,78	2,57	0,015		Algorithm converged.	-0,011	0,041	1,39		Algorithm converged.	0,79	2,46	0,2526		0,72		Algorithm converged.	0,41	1,27
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	3	1,6	184	10,1	4	2,2	0,75		Algorithm converged.	0,17	3,40	-0,005		Algorithm converged.	-0,033	0,023	0,75		Algorithm converged.	0,17	3,32	0,7091		1,33		Algorithm converged.	0,30	5,84
	PERICARDIAL EFFUSION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	4	0,8	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	0,031	*	WARNING: The relative Hessian convergence criterion of 18.885862968 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,121	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRINZMETAL ANGINA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS BRADYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	SINUS NODE DYSFUNCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS TACHYCARDIA	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	6	0,7	824	45,2	5	0,6	1,22		Algorithm converged.	0,37	4,00	0,001		Algorithm converged.	-0,007	0,009		1,21		Algorithm converged.	0,37	3,96	0,7472		0,82		Algorithm converged.	0,25	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	3	1,6	0,33		Algorithm converged.	0,03	3,22	-0,011		Algorithm converged.	-0,032	0,010		0,34		Algorithm converged.	0,04	3,19	0,3418		2,98		Algorithm converged.	0,31	28,42
	STRESS CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUPRAVENTRICULAR EXTRASYSTOLES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	USA/Canada	262	14,7	9	3,4	252	13,8	8	3,2	1,08		Algorithm converged.	0,41	2,86	0,003		Algorithm converged.	-0,028	0,034	1,08		Algorithm converged.	0,42	2,76	0,8689	-	0,92		Algorithm converged.	0,36	2,36
		Western Europe	814	45,7	25	3,1	824	45,2	17	2,1	1,50		Algorithm converged.	0,81	2,81	0,010		Algorithm converged.	-0,005	0,025	1,49		Algorithm converged.	0,81	2,74	0,2000		0,67		Algorithm converged.	0,37	1,23
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	8	4,4	184	10,1	3	1,6	2,76		Algorithm converged.	0,72	10,57	0,027		Algorithm converged.	-0,007	0,062	2,68		Algorithm converged.	0,72	9,95	0,1404		0,37		Algorithm converged.	0,10	1,38
	TACHYCARDIA PAROXYSMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRICUSPID VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICUSPID VALVE INCOMPETENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR EXTRASYSTOLES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	4	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CYSTIC FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHALANGEAL HYPOPLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TYPE V HYPERLIPIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	USA/Canada	262	14,7	24	9,2	252	13,8	27	10,7	0,84		Algorithm converged.	0,47	1,50	-0,016		Algorithm converged.	-0,067	0,036	0,85		Algorithm converged.	0,51	1,44	0,5563	-	1,17		Algorithm converged.	0,69	1,97
		Western Europe	814	45,7	66	8,1	824	45,2	68	8,3	0,98		Algorithm converged.	0,69	1,40	-0,001		Algorithm converged.	-0,028	0,025	0,98		Algorithm converged.	0,71	1,36	0,9151		1,02		Algorithm converged.	0,74	1,41
		Asia Pacific	482	27,0	22	4,6	517	28,4	27	5,2	0,87		Algorithm converged.	0,49	1,55	-0,007		Algorithm converged.	-0,033	0,020	0,87		Algorithm converged.	0,50	1,51	0,6307		1,14		Algorithm converged.	0,66	1,98
		Latin America	42	2,4	2	4,8	45	2,5	3	6,7	0,70		Algorithm converged.	0,11	4,41	-0,019		Algorithm converged.	-0,116	0,078	0,71		Algorithm converged.	0,13	4,07	0,7045		1,40		Algorithm converged.	0,25	7,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	8	4,4	184	10,1	6	3,3	1,36		Algorithm converged.	0,46	3,99	0,011		Algorithm converged.	-0,028	0,050		1,34		Algorithm converged.	0,47	3,79	0,5801		0,75		Algorithm converged.	0,26	2,11
	CERUMEN IMPACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CONDUCTIVE DEAFNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DEAFNESS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DEAFNESS BILATERAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEAFNESS UNILATERAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	EAR CONGESTION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-		1,04		Algorithm converged.	0,07	16,53	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	EAR DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-		2,08		Algorithm converged.	0,19	22,79	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EAR DISORDER	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EAR PAIN	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033	1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	4	0,5	824	45,2	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,004		Algorithm converged.	-0,011	0,004	0,58		Algorithm converged.	0,17	1,97	0,3810		1,73		Algorithm converged.	0,51	5,88
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTERNAL EAR INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOACUSIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENIERE'S DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIDDLE EAR INFLAMMATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTOLITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTOTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PRESBYACUSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINNITUS	USA/Canada	262	14,7	7	2,7	252	13,8	10	4,0	0,66		Algorithm converged.	0,25	1,77	-0,013		Algorithm converged.	-0,044	0,018	0,67		Algorithm converged.	0,26	1,74	0,4145	-	1,49		Algorithm converged.	0,57	3,84
		Western Europe	814	45,7	11	1,4	824	45,2	10	1,2	1,12		Algorithm converged.	0,47	2,64	0,001		Algorithm converged.	-0,010	0,012	1,11		Algorithm converged.	0,48	2,61	0,8044		0,90		Algorithm converged.	0,38	2,10
		Asia Pacific	482	27,0	11	2,3	517	28,4	8	1,5	1,49		Algorithm converged.	0,59	3,73	0,007		Algorithm converged.	-0,010	0,024	1,47		Algorithm converged.	0,60	3,64	0,3986		0,68		Algorithm converged.	0,28	1,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TYMPANIC MEMBRANE PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VERTIGO	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005		0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95
		Western Europe	814	45,7	40	4,9	824	45,2	45	5,5	0,89		Algorithm converged.	0,58	1,39	-0,005		Algorithm converged.	-0,027	0,016		0,90		Algorithm converged.	0,59	1,36	0,6179		1,11		Algorithm converged.	0,73	1,68
		Asia Pacific	482	27,0	7	1,5	517	28,4	10	1,9	0,75		Algorithm converged.	0,28	1,98	-0,005		Algorithm converged.	-0,021	0,011		0,75		Algorithm converged.	0,29	1,96	0,5576		1,33		Algorithm converged.	0,51	3,47
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	8	4,4	184	10,1	5	2,7	1,64		Algorithm converged.	0,53	5,10	0,017		Algorithm converged.	-0,021	0,054		1,61		Algorithm converged.	0,54	4,83	0,3962		0,62		Algorithm converged.	0,21	1,86
	VERTIGO POSITIONAL	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
ENDOCRINE DISORDER	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-		0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	7	0,9	824	45,2	14	1,7	0,50		Algorithm converged.	0,20	1,25	-0,008		Algorithm converged.	-0,019	0,002		0,51		Algorithm converged.	0,21	1,25	0,1390			1,98		Algorithm converged.	0,80	4,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005		0,43		Algorithm converged.	0,08	2,20	0,3104			2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034		1,34		Algorithm converged.	0,30	5,91	0,6984			0,75		Algorithm converged.	0,17	3,29
	AUTOIMMUNE THYROIDITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CUSHING'S SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CUSHINGOID	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GOITRE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	HYPERPARATHYROIDISM PRIMARY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPROLACTINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTHYROIDISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOTHYROIDISM	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	STEROID WITHDRAWAL SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	THYROID CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID MASS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	USA/Canada	262	14,7	107	40,8	252	13,8	110	43,7	0,89		Algorithm converged.	0,63	1,26	-0,028		Algorithm converged.	-0,114	0,057	0,94		Algorithm converged.	0,76	1,15	0,5189	0,1204	1,07		Algorithm converged.	0,87	1,31
		Western Europe	814	45,7	235	28,9	824	45,2	200	24,3	1,27		Algorithm converged.	1,02	1,58	0,046		Algorithm converged.	0,003	0,089	1,19		Algorithm converged.	1,01	1,40	0,0356		0,84		Algorithm converged.	0,72	0,99
		Asia Pacific	482	27,0	83	17,2	517	28,4	108	20,9	0,79		Algorithm converged.	0,57	1,08	-0,037		Algorithm converged.	-0,085	0,012	0,82		Algorithm converged.	0,64	1,07	0,1419		1,21		Algorithm converged.	0,94	1,57
		Latin America	42	2,4	4	9,5	45	2,5	6	13,3	0,68		Algorithm converged.	0,18	2,62	-0,038		Algorithm converged.	-0,171	0,095	0,71		Algorithm converged.	0,22	2,36	0,5805		1,40		Algorithm converged.	0,42	4,62
		Other	183	10,3	26	14,2	184	10,1	28	15,2	0,92		Algorithm converged.	0,52	1,64	-0,010		Algorithm converged.	-0,083	0,062	0,93		Algorithm converged.	0,57	1,53	0,7849		1,07		Algorithm converged.	0,65	1,75
	ABNORMAL SENSATION IN EYE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	AMAUROSIS FUGAX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	AMBLYOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHENOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTIGMATISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLEPHARITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLEPHARITIS ALLERGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLEPHAROSPASM	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARACT	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	5	1,0	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CATARACT CORTICAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHALAZION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVAL DEPOSIT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVAL HAEMORRHAGE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONJUNCTIVAL HYPERAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVITIS ALLERGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CORNEAL EXFOLIATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DACRYOSTENOSIS ACQUIRED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIPLOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY EYE	USA/Canada	262	14,7	15	5,7	252	13,8	20	7,9	0,70		Algorithm converged.	0,35	1,41	-0,022		Algorithm converged.	-0,066	0,022	0,72		Algorithm converged.	0,38	1,38	0,3223	-	1,39		Algorithm converged.	0,73	2,65
		Western Europe	814	45,7	56	6,9	824	45,2	34	4,1	1,72		Algorithm converged.	1,11	2,66	0,028		Algorithm converged.	0,005	0,050	1,67		Algorithm converged.	1,10	2,52	0,0158		0,60		Algorithm converged.	0,40	0,91
		Asia Pacific	482	27,0	16	3,3	517	28,4	19	3,7	0,90		Algorithm converged.	0,46	1,77	-0,004		Algorithm converged.	-0,026	0,019	0,90		Algorithm converged.	0,47	1,74	0,7602		1,11		Algorithm converged.	0,58	2,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	6	3,3	184	10,1	7	3,8	0,86		Algorithm converged.	0,28	2,60	-0,005		Algorithm converged.	-0,043	0,033	0,86		Algorithm converged.	0,30	2,52	0,7855		1,16		Algorithm converged.	0,40	3,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECTROPION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA OF EYELID	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE ALLERGY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE DISCHARGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	3	0,6	517	28,4	5	1,0	0,64		Algorithm converged.	0,15	2,70	-0,003		Algorithm converged.	-0,014	0,008		0,64		Algorithm converged.	0,15	2,68	0,5447		1,55		Algorithm converged.	0,37	6,47
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EYE DISORDER	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EYE HAEMORRHAGE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE IRRITATION	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	6	0,7	824	45,2	3	0,4	2,03		Algorithm converged.	0,51	8,15	0,004		Algorithm converged.	-0,003	0,011	2,02		Algorithm converged.	0,51	8,07	0,3173		0,49		Algorithm converged.	0,12	1,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	EYE MOVEMENT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	EYE OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	6	2,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	9	1,1	824	45,2	6	0,7	1,52		Algorithm converged.	0,54	4,30	0,004		Algorithm converged.	-0,005	0,013	1,52		Algorithm converged.	0,54	4,25	0,4260		0,66		Algorithm converged.	0,24	1,84
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE PRURITUS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	EYE SWELLING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID FUNCTION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID MARGIN CRUSTING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYELID PTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID SKIN DRYNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELIDS PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FOREIGN BODY SENSATION IN EYES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GLAUCOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATOCONUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	KERATOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
	LACRIMATION DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	USA/Canada	262	14,7	67	25,6	252	13,8	73	29,0	0,84		Algorithm converged.	0,57	1,24	-0,034		Algorithm converged.	-0,111	0,043	0,88		Algorithm converged.	0,67	1,17	0,3877	-	1,13		Algorithm converged.	0,85	1,50
		Western Europe	814	45,7	113	13,9	824	45,2	116	14,1	0,98		Algorithm converged.	0,74	1,30	-0,002		Algorithm converged.	-0,036	0,032	0,99		Algorithm converged.	0,78	1,25	0,9091		1,01		Algorithm converged.	0,80	1,29
		Asia Pacific	482	27,0	36	7,5	517	28,4	42	8,1	0,91		Algorithm converged.	0,57	1,45	-0,007		Algorithm converged.	-0,040	0,027	0,92		Algorithm converged.	0,60	1,41	0,7000		1,09		Algorithm converged.	0,71	1,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	12	6,6	184	10,1	15	8,2	0,79		Algorithm converged.	0,36	1,74	-0,016		Algorithm converged.	-0,069	0,037		0,80		Algorithm converged.	0,39	1,67	0,5594		1,24		Algorithm converged.	0,60	2,58
	MACULAR OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MEIBOMIAN GLAND DYSFUNCTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAMORPHOPSIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	NONINFECTIVE CONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR HYPERAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR HYPERTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPHTHALMOPLEGIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPTIC NERVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORBITAL GRANULOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIORBITAL OEDEMA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIORBITAL SWELLING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHOTOPHOBIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHOTOPSIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PTERYGIUM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RETINAL DETACHMENT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RETINAL VASCULAR DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCLERAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCLERAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULCERATIVE KERATITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UVEITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VERNAL KERATOCONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VISION BLURRED	USA/Canada	262	14,7	20	7,6	252	13,8	23	9,1	0,82		Algorithm converged.	0,44	1,54	-0,015		Algorithm converged.	-0,063	0,033		0,84		Algorithm converged.	0,47	1,48	0,5416	-	1,20		Algorithm converged.	0,67	2,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	10	1,2	824	45,2	8	1,0	1,27		Algorithm converged.	0,50	3,23	0,003		Algorithm converged.	-0,008	0,013	1,27		Algorithm converged.	0,50	3,19	0,6179		0,79		Algorithm converged.	0,31	1,99
		Asia Pacific	482	27,0	8	1,7	517	28,4	13	2,5	0,65		Algorithm converged.	0,27	1,59	-0,009		Algorithm converged.	-0,026	0,009	0,66		Algorithm converged.	0,28	1,58	0,3504		1,51		Algorithm converged.	0,63	3,62
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VISUAL ACUITY REDUCED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	10	1,2	824	45,2	5	0,6	2,04		Algorithm converged.	0,69	5,99	0,006		Algorithm converged.	-0,003	0,015	2,02		Algorithm converged.	0,70	5,90	0,1960		0,49		Algorithm converged.	0,17	1,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VISUAL FIELD DEFECT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	VISUAL IMPAIRMENT	USA/Canada	262	14,7	10	3,8	252	13,8	7	2,8	1,39		Algorithm converged.	0,52	3,71	0,010		Algorithm converged.	-0,020	0,041	1,37		Algorithm converged.	0,53	3,55	0,5122	-	0,73		Algorithm converged.	0,28	1,88	
		Western Europe	814	45,7	25	3,1	824	45,2	13	1,6	1,98		Algorithm converged.	1,00	3,89	0,015		Algorithm converged.	0,000	0,030	1,95		Algorithm converged.	1,00	3,78	0,0490		0,51		Algorithm converged.	0,26	1,00	
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	VITREOUS DETACHMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS FLOATERS	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2	4,32		Algorithm converged.	0,48	38,77	0,006		Algorithm converged.	-0,003	0,015	4,29		Algorithm converged.	0,48	38,25	0,1920		0,23		Algorithm converged.	0,03	2,08
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VITREOUS OPACITIES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	XEROPHTHALMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	261	99,6	252	13,8	242	96,0	10,79		Algorithm converged.	1,37	84,88	0,036		Algorithm converged.	0,011	0,061	1,04		Algorithm converged.	1,01	1,06	0,0061	0,5891	0,96		Algorithm converged.	0,94	0,99
		Western Europe	814	45,7	779	95,7	824	45,2	751	91,1	2,16		Algorithm converged.	1,43	3,28	0,046		Algorithm converged.	0,022	0,069	1,05		Algorithm converged.	1,02	1,08	0,0002		0,95		Algorithm converged.	0,93	0,98
		Asia Pacific	482	27,0	457	94,8	517	28,4	464	89,7	2,09		Algorithm converged.	1,28	3,42	0,051		Algorithm converged.	0,018	0,083	1,06		Algorithm converged.	1,02	1,09	0,0027		0,95		Algorithm converged.	0,91	0,98
		Latin America	42	2,4	33	78,6	45	2,5	29	64,4	2,02		Algorithm converged.	0,78	5,27	0,141		Algorithm converged.	-0,046	0,328	1,22		Algorithm converged.	0,93	1,59	0,1478		0,82		Algorithm converged.	0,63	1,07
		Other	183	10,3	157	85,8	184	10,1	144	78,3	1,68		Algorithm converged.	0,97	2,89	0,075		Algorithm converged.	-0,003	0,153	1,10		Algorithm converged.	1,00	1,21	0,0615		0,91		Algorithm converged.	0,83	1,00
	ABDOMINAL DISCOMFORT	USA/Canada	262	14,7	6	2,3	252	13,8	1	0,4	5,88		Algorithm converged.	0,70	49,21	0,019		Algorithm converged.	-0,001	0,039	5,77		Algorithm converged.	0,70	47,60	0,1035	-	0,17		Algorithm converged.	0,02	1,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006	0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58						
		Asia Pacific	482	27,0	8	1,7	517	28,4	20	3,9	0,42		Algorithm converged.	0,18	0,96	-0,022		Algorithm converged.	-0,042	-0,002	0,43		Algorithm converged.	0,19	0,96	0,0407		2,33		Algorithm converged.	1,04	5,24						
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	ABDOMINAL DISTENSION	USA/Canada	262	14,7	8	3,1	252	13,8	14	5,6	0,54		Algorithm converged.	0,22	1,30	-0,025		Algorithm converged.	-0,060	0,010	0,55		Algorithm converged.	0,23	1,29	0,1682	-	1,82		Algorithm converged.	0,78	4,26						
		Western Europe	814	45,7	15	1,8	824	45,2	11	1,3	1,39		Algorithm converged.	0,63	3,04	0,005		Algorithm converged.	-0,007	0,017	1,38		Algorithm converged.	0,64	2,99	0,4131		0,72		Algorithm converged.	0,33	1,57						
		Asia Pacific	482	27,0	30	6,2	517	28,4	16	3,1	2,08		Algorithm converged.	1,12	3,86	0,031		Algorithm converged.	0,005	0,058	2,01		Algorithm converged.	1,11	3,64	0,0211		0,50		Algorithm converged.	0,27	0,90						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL HERNIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL PAIN	USA/Canada	262	14,7	31	11,8	252	13,8	38	15,1	0,76		Algorithm converged.	0,45	1,26	-0,032		Algorithm converged.	-0,091	0,027		0,78		Algorithm converged.	0,50	1,22	0,2819	0,5057	1,27		Algorithm converged.	0,82	1,98
		Western Europe	814	45,7	106	13,0	824	45,2	98	11,9	1,11		Algorithm converged.	0,83	1,49	0,011		Algorithm converged.	-0,021	0,043		1,09		Algorithm converged.	0,85	1,42	0,4892		0,91		Algorithm converged.	0,71	1,18
		Asia Pacific	482	27,0	46	9,5	517	28,4	36	7,0	1,41		Algorithm converged.	0,89	2,22	0,026		Algorithm converged.	-0,008	0,060		1,37		Algorithm converged.	0,90	2,08	0,1395		0,73		Algorithm converged.	0,48	1,11
		Latin America	42	2,4	6	14,3	45	2,5	6	13,3	1,08		Algorithm converged.	0,32	3,67	0,010		Algorithm converged.	-0,136	0,155		1,07		Algorithm converged.	0,37	3,06	0,8976		0,93		Algorithm converged.	0,33	2,67
		Other	183	10,3	11	6,0	184	10,1	11	6,0	1,01		Algorithm converged.	0,42	2,38	0,000		Algorithm converged.	-0,048	0,049		1,01		Algorithm converged.	0,45	2,26	0,9895		0,99		Algorithm converged.	0,44	2,24
	ABDOMINAL PAIN LOWER	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005		0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL PAIN UPPER	USA/Canada	262	14,7	11	4,2	252	13,8	12	4,8	0,88		Algorithm converged.	0,38	2,02	-0,006		Algorithm converged.	-0,041	0,030	0,88		Algorithm converged.	0,40	1,96	0,7576	-	1,13		Algorithm converged.	0,51	2,52
		Western Europe	814	45,7	114	14,0	824	45,2	92	11,2	1,30		Algorithm converged.	0,97	1,74	0,028		Algorithm converged.	-0,004	0,061	1,25		Algorithm converged.	0,97	1,62	0,0840		0,80		Algorithm converged.	0,62	1,03
		Asia Pacific	482	27,0	37	7,7	517	28,4	40	7,7	0,99		Algorithm converged.	0,62	1,58	-0,001		Algorithm converged.	-0,034	0,032	0,99		Algorithm converged.	0,65	1,52	0,9714		1,01		Algorithm converged.	0,66	1,55
		Latin America	42	2,4	5	11,9	45	2,5	4	8,9	1,39		Algorithm converged.	0,35	5,55	0,030		Algorithm converged.	-0,098	0,159	1,34		Algorithm converged.	0,39	4,65	0,6458		0,75		Algorithm converged.	0,21	2,60
		Other	183	10,3	8	4,4	184	10,1	8	4,3	1,01		Algorithm converged.	0,37	2,74	0,000		Algorithm converged.	-0,042	0,042	1,01		Algorithm converged.	0,39	2,62	0,9911		0,99		Algorithm converged.	0,38	2,59
	ABDOMINAL RIGIDITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ABNORMAL FAECES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACID PEPTIC DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AEROPHAGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAESTHESIA ORAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ERYTHEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FISSURE	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	8	1,0	824	45,2	8	1,0	1,01		Algorithm converged.	0,38	2,71	0,000		Algorithm converged.	-0,009	0,010	1,01		Algorithm converged.	0,38	2,68	0,9804		0,99		Algorithm converged.	0,37	2,62
		Asia Pacific	482	27,0	5	1,0	517	28,4	2	0,4	2,70		Algorithm converged.	0,52	13,98	0,007		Algorithm converged.	-0,004	0,017	2,68		Algorithm converged.	0,52	13,76	0,2371		0,37		Algorithm converged.	0,07	1,91
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FISTULA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL HAEMORRHAGE	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	5	1,0	517	28,4	8	1,5	0,67		Algorithm converged.	0,22	2,05	-0,005		Algorithm converged.	-0,019	0,009	0,67		Algorithm converged.	0,22	2,04	0,4803		1,49		Algorithm converged.	0,49	4,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INCONTINENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	6	0,7	824	45,2	4	0,5	1,52		Algorithm converged.	0,43	5,41	0,003		Algorithm converged.	-0,005	0,010	1,52		Algorithm converged.	0,43	5,36	0,5164		0,66		Algorithm converged.	0,19	2,33
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL SKIN TAGS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGULAR CHEILITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,005		Algorithm converged.	-0,011	0,001	0,20		Algorithm converged.	0,02	1,73	0,1444		4,94		Algorithm converged.	0,58	42,19
		Asia Pacific	482	27,0	15	3,1	517	28,4	8	1,5	2,04		Algorithm converged.	0,86	4,86	0,016		Algorithm converged.	-0,003	0,034	2,01		Algorithm converged.	0,86	4,70	0,1068		0,50		Algorithm converged.	0,21	1,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANORECTAL DISCOMFORT	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009	1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANORECTAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	22	2,7	824	45,2	15	1,8	1,50		Algorithm converged.	0,77	2,91	0,009		Algorithm converged.	-0,006	0,023	1,48		Algorithm converged.	0,78	2,84	0,2327		0,67		Algorithm converged.	0,35	1,29
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	APTYALISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASCITES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREATH ODOUR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	CHANGE OF BOWEL HABIT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHAPPED LIPS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEILITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	3	0,6	1,07		Algorithm converged.	0,22	5,34	0,000		Algorithm converged.	-0,009	0,010		1,07		Algorithm converged.	0,22	5,29	0,9314		0,93		Algorithm converged.	0,19	4,60
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHRONIC GASTRITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	COLITIS	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010		0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002085 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS ISCHAEMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	USA/Canada	262	14,7	99	37,8	252	13,8	122	48,4	0,65		Algorithm converged.	0,46	0,92	-0,106		Algorithm converged.	-0,191	-0,021		0,78		Algorithm converged.	0,64	0,95	0,0157	-	1,28		Algorithm converged.	1,05	1,57
		Western Europe	814	45,7	243	29,9	824	45,2	252	30,6	0,97		Algorithm converged.	0,78	1,19	-0,007		Algorithm converged.	-0,052	0,037		0,98		Algorithm converged.	0,84	1,13	0,7477		1,02		Algorithm converged.	0,88	1,19
		Asia Pacific	482	27,0	151	31,3	517	28,4	154	29,8	1,08		Algorithm converged.	0,82	1,41	0,015		Algorithm converged.	-0,042	0,073		1,05		Algorithm converged.	0,87	1,27	0,5972		0,95		Algorithm converged.	0,79	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	7	15,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	13	7,1	184	10,1	13	7,1	1,01		Algorithm converged.	0,45	2,23	0,000		Algorithm converged.	-0,052	0,053	1,01		Algorithm converged.	0,48	2,11	0,9885		0,99		Algorithm converged.	0,47	2,09
	DENTAL CARIES	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	5	1,0	517	28,4	8	1,5	0,67		Algorithm converged.	0,22	2,05	-0,005		Algorithm converged.	-0,019	0,009	0,67		Algorithm converged.	0,22	2,04	0,4803		1,49		Algorithm converged.	0,49	4,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	USA/Canada	262	14,7	220	84,0	252	13,8	168	66,7	2,62		Algorithm converged.	1,72	3,99	0,173		Algorithm converged.	0,100	0,246	1,26		Algorithm converged.	1,14	1,39	<.0001	0,0020	0,79		Algorithm converged.	0,72	0,88
		Western Europe	814	45,7	614	75,4	824	45,2	379	46,0	3,60		Algorithm converged.	2,92	4,45	0,294		Algorithm converged.	0,249	0,339	1,64		Algorithm converged.	1,51	1,78	<.0001		0,61		Algorithm converged.	0,56	0,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	307	63,7	517	28,4	213	41,2	2,50		Algorithm converged.	1,94	3,23	0,225		Algorithm converged.	0,165	0,285		1,55		Algorithm converged.	1,37	1,75	<.0001		0,65		Algorithm converged.	0,57	0,73
		Latin America	42	2,4	25	59,5	45	2,5	16	35,6	2,67		Algorithm converged.	1,12	6,34	0,240		Algorithm converged.	0,036	0,444		1,67		Algorithm converged.	1,05	2,67	0,0301		0,60		Algorithm converged.	0,37	0,95
		Other	183	10,3	89	48,6	184	10,1	48	26,1	2,68		Algorithm converged.	1,73	4,16	0,225		Algorithm converged.	0,129	0,322		1,86		Algorithm converged.	1,40	2,48	<.0001		0,54		Algorithm converged.	0,40	0,71
	DIARRHOEA HAEMORRHAGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM INTESTINAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM OESOPHAGEAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY MOUTH	USA/Canada	262	14,7	19	7,3	252	13,8	21	8,3	0,86		Algorithm converged.	0,45	1,64	-0,011		Algorithm converged.	-0,057	0,036		0,87		Algorithm converged.	0,48	1,58	0,6476	-	1,15		Algorithm converged.	0,63	2,09
		Western Europe	814	45,7	64	7,9	824	45,2	53	6,4	1,24		Algorithm converged.	0,85	1,81	0,014		Algorithm converged.	-0,011	0,039		1,22		Algorithm converged.	0,86	1,74	0,2620		0,82		Algorithm converged.	0,58	1,16
		Asia Pacific	482	27,0	17	3,5	517	28,4	18	3,5	1,01		Algorithm converged.	0,52	1,99	0,000		Algorithm converged.	-0,022	0,023		1,01		Algorithm converged.	0,53	1,94	0,9689		0,99		Algorithm converged.	0,51	1,89
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	7	3,8	184	10,1	10	5,4	0,69		Algorithm converged.	0,26	1,86	-0,016		Algorithm converged.	-0,059	0,027		0,70		Algorithm converged.	0,27	1,81	0,4658		1,42		Algorithm converged.	0,55	3,65
	DUODENAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DYSCHEZIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPEPSIA	USA/Canada	262	14,7	62	23,7	252	13,8	75	29,8	0,73		Algorithm converged.	0,49	1,08	-0,061		Algorithm converged.	-0,137	0,015		0,80		Algorithm converged.	0,60	1,06	0,1194	-	1,26		Algorithm converged.	0,94	1,68
		Western Europe	814	45,7	120	14,7	824	45,2	102	12,4	1,22		Algorithm converged.	0,92	1,63	0,024		Algorithm converged.	-0,010	0,057		1,19		Algorithm converged.	0,93	1,52	0,1631		0,84		Algorithm converged.	0,66	1,07
		Asia Pacific	482	27,0	40	8,3	517	28,4	49	9,5	0,86		Algorithm converged.	0,56	1,34	-0,012		Algorithm converged.	-0,047	0,023		0,88		Algorithm converged.	0,59	1,30	0,5138		1,14		Algorithm converged.	0,77	1,70
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125		1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	18	9,8	184	10,1	18	9,8	1,01		Algorithm converged.	0,51	2,00	0,001		Algorithm converged.	-0,060	0,061		1,01		Algorithm converged.	0,54	1,87	0,9863		0,99		Algorithm converged.	0,53	1,85
	DYSPHAGIA	USA/Canada	262	14,7	15	5,7	252	13,8	3	1,2	5,04		Algorithm converged.	1,44	17,63	0,045		Algorithm converged.	0,014	0,077		4,81		Algorithm converged.	1,41	16,41	0,0122	-	0,21		Algorithm converged.	0,06	0,71
		Western Europe	814	45,7	36	4,4	824	45,2	35	4,2	1,04		Algorithm converged.	0,65	1,68	0,002		Algorithm converged.	-0,018	0,021		1,04		Algorithm converged.	0,66	1,64	0,8619		0,96		Algorithm converged.	0,61	1,51
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018		0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	ENTERITIS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPIGASTRIC DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERUCTATION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAECALOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAECES SOFT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLATULENCE	USA/Canada	262	14,7	9	3,4	252	13,8	9	3,6	0,96		Algorithm converged.	0,37	2,46	-0,001		Algorithm converged.	-0,033	0,030	0,96		Algorithm converged.	0,39	2,38	0,9330	-	1,04		Algorithm converged.	0,42	2,58
		Western Europe	814	45,7	16	2,0	824	45,2	19	2,3	0,85		Algorithm converged.	0,43	1,66	-0,003		Algorithm converged.	-0,017	0,011	0,85		Algorithm converged.	0,44	1,65	0,6344		1,17		Algorithm converged.	0,61	2,27
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	1	0,5	3,05		Algorithm converged.	0,31	29,60	0,011		Algorithm converged.	-0,010	0,032	3,02		Algorithm converged.	0,32	28,73	0,3370		0,33		Algorithm converged.	0,03	3,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	FOOD POISONING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	FREQUENT BOWEL MOVEMENTS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	FUNCTIONAL GASTROINTESTINAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC DILATATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC MUCOSA ERYTHEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC POLYPS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010	0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	23	2,8	824	45,2	18	2,2	1,30		Algorithm converged.	0,70	2,43	0,006		Algorithm converged.	-0,009	0,022	1,29		Algorithm converged.	0,70	2,38	0,4077		0,77		Algorithm converged.	0,42	1,42
		Asia Pacific	482	27,0	13	2,7	517	28,4	8	1,5	1,76		Algorithm converged.	0,72	4,29	0,011		Algorithm converged.	-0,006	0,029	1,74		Algorithm converged.	0,73	4,17	0,2117		0,57		Algorithm converged.	0,24	1,37
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138	3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS EROSIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6	0,61		Algorithm converged.	0,14	2,54	-0,002		Algorithm converged.	-0,009	0,004	0,61		Algorithm converged.	0,15	2,53	0,4938		1,65		Algorithm converged.	0,39	6,87
		Asia Pacific	482	27,0	8	1,7	517	28,4	9	1,7	0,95		Algorithm converged.	0,36	2,49	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,37	2,45	0,9212		1,05		Algorithm converged.	0,41	2,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL MOTILITY DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	GASTROINTESTINAL MUCOSAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	14	1,7	824	45,2	4	0,5	3,59		Algorithm converged.	1,18	10,95	0,012		Algorithm converged.	0,002	0,022	3,54		Algorithm converged.	1,17	10,72	0,0251		0,28		Algorithm converged.	0,09	0,85
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL SOUNDS ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROOESOPHAGEAL REFLUX DISEASE	USA/Canada	262	14,7	27	10,3	252	13,8	22	8,7	1,20		Algorithm converged.	0,66	2,17	0,016		Algorithm converged.	-0,035	0,066	1,18		Algorithm converged.	0,69	2,02	0,5439	-	0,85		Algorithm converged.	0,50	1,45
		Western Europe	814	45,7	39	4,8	824	45,2	36	4,4	1,10		Algorithm converged.	0,69	1,75	0,004		Algorithm converged.	-0,016	0,024	1,10		Algorithm converged.	0,70	1,71	0,6828		0,91		Algorithm converged.	0,59	1,42
		Asia Pacific	482	27,0	22	4,6	517	28,4	23	4,4	1,03		Algorithm converged.	0,56	1,87	0,001		Algorithm converged.	-0,025	0,027	1,03		Algorithm converged.	0,58	1,82	0,9299		0,97		Algorithm converged.	0,55	1,73
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	GINGIVAL ATROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL BLEEDING	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005	0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011	1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21
		Asia Pacific	482	27,0	7	1,5	517	28,4	10	1,9	0,75		Algorithm converged.	0,28	1,98	-0,005		Algorithm converged.	-0,021	0,011	0,75		Algorithm converged.	0,29	1,96	0,5576		1,33		Algorithm converged.	0,51	3,47
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVAL SWELLING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	9	1,7	0,35		Algorithm converged.	0,10	1,31	-0,011		Algorithm converged.	-0,024	0,002	0,36		Algorithm converged.	0,10	1,31	0,1212		2,80		Algorithm converged.	0,76	10,27
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLOSSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GLOSSODYNIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMATOCHEZIA	USA/Canada	262	14,7	1	0,4	252	13,8	5	2,0	0,19		Algorithm converged.	0,02	1,63	-0,016		Algorithm converged.	-0,035	0,003	0,19		Algorithm converged.	0,02	1,64	0,1311	-	5,20		Algorithm converged.	0,61	44,19
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	USA/Canada	262	14,7	9	3,4	252	13,8	5	2,0	1,76		Algorithm converged.	0,58	5,32	0,015		Algorithm converged.	-0,013	0,042	1,73		Algorithm converged.	0,59	5,10	0,3190	-	0,58		Algorithm converged.	0,20	1,70
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63
		Asia Pacific	482	27,0	4	0,8	517	28,4	5	1,0	0,86		Algorithm converged.	0,23	3,21	-0,001		Algorithm converged.	-0,013	0,010	0,86		Algorithm converged.	0,23	3,18	0,8187		1,17		Algorithm converged.	0,31	4,31
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	HAEMORRHOIDS	USA/Canada	262	14,7	26	9,9	252	13,8	15	6,0	1,74		Algorithm converged.	0,90	3,37	0,040		Algorithm converged.	-0,007	0,086	1,67		Algorithm converged.	0,90	3,07	0,1014	-	0,60		Algorithm converged.	0,33	1,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	63	7,7	824	45,2	50	6,1	1,30		Algorithm converged.	0,88	1,91	0,017		Algorithm converged.	-0,008	0,041		1,28		Algorithm converged.	0,89	1,83	0,1833		0,78		Algorithm converged.	0,55	1,12
		Asia Pacific	482	27,0	36	7,5	517	28,4	23	4,4	1,73		Algorithm converged.	1,01	2,97	0,030		Algorithm converged.	0,001	0,060		1,68		Algorithm converged.	1,01	2,79	0,0457		0,60		Algorithm converged.	0,36	0,99
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	8	4,4	184	10,1	8	4,3	1,01		Algorithm converged.	0,37	2,74	0,000		Algorithm converged.	-0,042	0,042		1,01		Algorithm converged.	0,39	2,62	0,9911		0,99		Algorithm converged.	0,38	2,59
	HIATUS HERNIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERAESTHESIA TEETH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERCHLORHYDRIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOAESTHESIA ORAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IMPAIRED GASTRIC EMPTYING	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRRITABLE BOWEL SYNDROME	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARGE INTESTINAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARGE INTESTINE POLYP	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP DRY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIP EROSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIP PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP SWELLING	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	4	0,8	0,27		Algorithm converged.	0,03	2,39	-0,006		Algorithm converged.	-0,014	0,003	0,27		Algorithm converged.	0,03	2,39	0,2383		3,73		Algorithm converged.	0,42	33,25
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOOSE TOOTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MELAENA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MOUTH HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MOUTH ULCERATION	USA/Canada	262	14,7	3	1,1	252	13,8	5	2,0	0,57		Algorithm converged.	0,14	2,42	-0,008		Algorithm converged.	-0,030	0,013	0,58		Algorithm converged.	0,14	2,39	0,4483	-	1,73		Algorithm converged.	0,42	7,18
		Western Europe	814	45,7	21	2,6	824	45,2	31	3,8	0,68		Algorithm converged.	0,39	1,19	-0,012		Algorithm converged.	-0,029	0,005	0,69		Algorithm converged.	0,40	1,18	0,1752		1,46		Algorithm converged.	0,85	2,52
		Asia Pacific	482	27,0	28	5,8	517	28,4	23	4,4	1,32		Algorithm converged.	0,75	2,33	0,014		Algorithm converged.	-0,014	0,041	1,31		Algorithm converged.	0,76	2,23	0,3305		0,77		Algorithm converged.	0,45	1,31
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAUSEA	USA/Canada	262	14,7	206	78,6	252	13,8	189	75,0	1,23		Algorithm converged.	0,81	1,85	0,036		Algorithm converged.	-0,037	0,109		1,05		Algorithm converged.	0,95	1,15	0,3311	0,9755	0,95		Algorithm converged.	0,87	1,05
		Western Europe	814	45,7	560	68,8	824	45,2	533	64,7	1,20		Algorithm converged.	0,98	1,48	0,041		Algorithm converged.	-0,004	0,087		1,06		Algorithm converged.	0,99	1,14	0,0777		0,94		Algorithm converged.	0,88	1,01
		Asia Pacific	482	27,0	332	68,9	517	28,4	332	64,2	1,23		Algorithm converged.	0,95	1,61	0,047		Algorithm converged.	-0,012	0,105		1,07		Algorithm converged.	0,98	1,17	0,1184		0,93		Algorithm converged.	0,85	1,02
		Latin America	42	2,4	22	52,4	45	2,5	21	46,7	1,26		Algorithm converged.	0,54	2,92	0,057		Algorithm converged.	-0,153	0,267		1,12		Algorithm converged.	0,73	1,72	0,5943		0,89		Algorithm converged.	0,58	1,36
		Other	183	10,3	113	61,7	184	10,1	112	60,9	1,04		Algorithm converged.	0,68	1,58	0,009		Algorithm converged.	-0,091	0,108		1,01		Algorithm converged.	0,86	1,19	0,8627		0,99		Algorithm converged.	0,84	1,16
	NONINFECTIVE GINGIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ODYNOPHAGIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	10	1,2	824	45,2	9	1,1	1,13		Algorithm converged.	0,46	2,79	0,001		Algorithm converged.	-0,009	0,012		1,12		Algorithm converged.	0,46	2,75	0,7969		0,89		Algorithm converged.	0,36	2,18
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	3	7,1	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OEDEMA MOUTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OESOPHAGEAL DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OESOPHAGEAL SPASM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGITIS	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	19	2,3	824	45,2	12	1,5	1,62		Algorithm converged.	0,78	3,35	0,009		Algorithm converged.	-0,004	0,022	1,60		Algorithm converged.	0,78	3,28	0,1967		0,62		Algorithm converged.	0,30	1,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002085 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DYSAESTHESIA	USA/Canada	262	14,7	0	0,0	252	13,8	4	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL LICHEN PLANUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL MUCOSA HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL MUCOSAL BLISTERING	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORAL MUCOSAL ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	ORAL MUCOSAL ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE					
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	ORAL PAIN	USA/Canada	262	14,7	10	3,8	252	13,8	9	3,6	1,07		Algorithm converged.	0,43	2,68	0,002		Algorithm converged.	-0,030	0,035		1,07		Algorithm converged.	0,44	2,59	0,8829	-		0,94		Algorithm converged.	0,39	2,26					
		Western Europe	814	45,7	14	1,7	824	45,2	19	2,3	0,74		Algorithm converged.	0,37	1,49	-0,006		Algorithm converged.	-0,019	0,008		0,75		Algorithm converged.	0,38	1,48	0,4005			1,34		Algorithm converged.	0,68	2,66					
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004		0,36		Algorithm converged.	0,04	3,43	0,3724			2,80		Algorithm converged.	0,29	26,80					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018		0,67		Algorithm converged.	0,11	3,96	0,6591			1,49		Algorithm converged.	0,25	8,82					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OVERFLOW DIARRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PANCREATIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	1	0,5	3,05		Algorithm converged.	0,31	29,60	0,011		Algorithm converged.	-0,010	0,032		3,02		Algorithm converged.	0,32	28,73	0,3370			0,33		Algorithm converged.	0,03	3,16
	PANCREATITIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-		2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PARAESTHESIA ORAL	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	5	0,6	824	45,2	1	0,1	5,09		Algorithm converged.	0,59	43,63	0,005		Algorithm converged.	-0,001	0,011	5,06		Algorithm converged.	0,59	43,23	0,1384		0,20		Algorithm converged.	0,02	1,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAROTID GLAND ENLARGEMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PEPTIC ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTAL DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PROCTALGIA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016		1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PROCTITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	5	1,9	252	13,8	7	2,8	0,68		Algorithm converged.	0,21	2,17	-0,009		Algorithm converged.	-0,035	0,018	0,69		Algorithm converged.	0,22	2,14	0,5167	-	1,46		Algorithm converged.	0,47	4,53
		Western Europe	814	45,7	17	2,1	824	45,2	8	1,0	2,18		Algorithm converged.	0,93	5,07	0,011		Algorithm converged.	-0,001	0,023	2,15		Algorithm converged.	0,93	4,96	0,0721		0,46		Algorithm converged.	0,20	1,07
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL TENESMUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	REFLUX GASTRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	RETCHING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALIVARY GLAND PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALIVARY HYPERSECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	USA/Canada	262	14,7	75	28,6	252	13,8	67	26,6	1,11		Algorithm converged.	0,75	1,63	0,020		Algorithm converged.	-0,057	0,098	1,08		Algorithm converged.	0,81	1,43	0,6056	-	0,93		Algorithm converged.	0,70	1,23
		Western Europe	814	45,7	224	27,5	824	45,2	176	21,4	1,40		Algorithm converged.	1,11	1,75	0,062		Algorithm converged.	0,020	0,103	1,29		Algorithm converged.	1,08	1,53	0,0039		0,78		Algorithm converged.	0,65	0,92
		Asia Pacific	482	27,0	166	34,4	517	28,4	157	30,4	1,20		Algorithm converged.	0,92	1,57	0,041		Algorithm converged.	-0,017	0,099	1,13		Algorithm converged.	0,95	1,36	0,1693		0,88		Algorithm converged.	0,74	1,06
		Latin America	42	2,4	7	16,7	45	2,5	2	4,4	4,30		Algorithm converged.	0,84	22,03	0,122		Algorithm converged.	-0,006	0,250	3,75		Algorithm converged.	0,82	17,05	0,0871		0,27		Algorithm converged.	0,06	1,21
		Other	183	10,3	43	23,5	184	10,1	28	15,2	1,71		Algorithm converged.	1,01	2,90	0,083		Algorithm converged.	0,002	0,163	1,54		Algorithm converged.	1,00	2,37	0,0475		0,65		Algorithm converged.	0,42	1,00
	STRAWBERRY TONGUE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SUBILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SWOLLEN TONGUE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE BLISTERING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE COATED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE DISCOLOURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TONGUE DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TONGUE ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE ULCERATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DISCOLOURATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH IMPACTED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH LOSS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TOOTHACHE	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033		1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	17	2,1	824	45,2	23	2,8	0,74		Algorithm converged.	0,39	1,40	-0,007		Algorithm converged.	-0,022	0,008		0,75		Algorithm converged.	0,40	1,39	0,3587		1,34		Algorithm converged.	0,72	2,48
		Asia Pacific	482	27,0	12	2,5	517	28,4	9	1,7	1,44		Algorithm converged.	0,60	3,45	0,007		Algorithm converged.	-0,010	0,025		1,43		Algorithm converged.	0,61	3,36	0,4123		0,70		Algorithm converged.	0,30	1,64

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731458976 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	4	2,2	0,50		Algorithm converged.	0,09	2,75	-0,011		Algorithm converged.	-0,037	0,015		0,50		Algorithm converged.	0,09	2,71	0,4238		1,99		Algorithm converged.	0,37	10,73
	UMBILICAL HERNIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOMITING	USA/Canada	262	14,7	101	38,5	252	13,8	94	37,3	1,05		Algorithm converged.	0,74	1,51	0,012		Algorithm converged.	-0,071	0,096	1,03		Algorithm converged.	0,83	1,29	0,7707	0,5695	0,97		Algorithm converged.	0,78	1,21
		Western Europe	814	45,7	230	28,3	824	45,2	215	26,1	1,12		Algorithm converged.	0,90	1,39	0,022		Algorithm converged.	-0,021	0,065	1,08		Algorithm converged.	0,92	1,27	0,3253		0,92		Algorithm converged.	0,79	1,08
		Asia Pacific	482	27,0	203	42,1	517	28,4	188	36,4	1,27		Algorithm converged.	0,99	1,64	0,058		Algorithm converged.	-0,003	0,118	1,16		Algorithm converged.	0,99	1,35	0,0629		0,86		Algorithm converged.	0,74	1,01
		Latin America	42	2,4	14	33,3	45	2,5	9	20,0	2,00		Algorithm converged.	0,76	5,29	0,133		Algorithm converged.	-0,051	0,318	1,67		Algorithm converged.	0,81	3,44	0,1668		0,60		Algorithm converged.	0,29	1,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	57	31,1	184	10,1	60	32,6	0,93		Algorithm converged.	0,60	1,45	-0,015		Algorithm converged.	-0,110	0,081		0,96		Algorithm converged.	0,71	1,29	0,7640		1,05		Algorithm converged.	0,78	1,41
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	247	94,3	252	13,8	236	93,7	1,12		Algorithm converged.	0,54	2,31	0,006		Algorithm converged.	-0,035	0,047		1,01		Algorithm converged.	0,96	1,05	0,7667	0,2382	0,99		Algorithm converged.	0,95	1,04
		Western Europe	814	45,7	736	90,4	824	45,2	730	88,6	1,22		Algorithm converged.	0,88	1,67	0,018		Algorithm converged.	-0,011	0,048		1,02		Algorithm converged.	0,99	1,06	0,2282		0,98		Algorithm converged.	0,95	1,01
		Asia Pacific	482	27,0	367	76,1	517	28,4	384	74,3	1,11		Algorithm converged.	0,83	1,47	0,019		Algorithm converged.	-0,035	0,072		1,03		Algorithm converged.	0,95	1,10	0,4946		0,98		Algorithm converged.	0,91	1,05
		Latin America	42	2,4	26	61,9	45	2,5	22	48,9	1,70		Algorithm converged.	0,72	3,99	0,130		Algorithm converged.	-0,077	0,337		1,27		Algorithm converged.	0,86	1,85	0,2252		0,79		Algorithm converged.	0,54	1,16
		Other	183	10,3	124	67,8	184	10,1	104	56,5	1,62		Algorithm converged.	1,06	2,47	0,112		Algorithm converged.	0,014	0,211		1,20		Algorithm converged.	1,02	1,41	0,0277		0,83		Algorithm converged.	0,71	0,98
	ADVERSE DRUG REACTION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	APPLICATION SITE RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ASTHENIA	USA/Canada	262	14,7	11	4,2	252	13,8	16	6,3	0,65		Algorithm converged.	0,29	1,42	-0,022		Algorithm converged.	-0,060	0,017		0,66		Algorithm converged.	0,31	1,40	0,2784	0,3039	1,51		Algorithm converged.	0,72	3,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	272	33,4	824	45,2	269	32,6	1,04		Algorithm converged.	0,84	1,27	0,008		Algorithm converged.	-0,038	0,053	1,02		Algorithm converged.	0,89	1,17	0,7406		0,98		Algorithm converged.	0,85	1,12
		Asia Pacific	482	27,0	42	8,7	517	28,4	39	7,5	1,17		Algorithm converged.	0,74	1,84	0,012		Algorithm converged.	-0,022	0,046	1,16		Algorithm converged.	0,76	1,75	0,4987		0,87		Algorithm converged.	0,57	1,31
		Latin America	42	2,4	12	28,6	45	2,5	6	13,3	2,60		Algorithm converged.	0,87	7,73	0,152		Algorithm converged.	-0,017	0,321	2,14		Algorithm converged.	0,88	5,19	0,0915		0,47		Algorithm converged.	0,19	1,13
		Other	183	10,3	43	23,5	184	10,1	37	20,1	1,22		Algorithm converged.	0,74	2,01	0,034		Algorithm converged.	-0,051	0,118	1,17		Algorithm converged.	0,79	1,72	0,4326		0,86		Algorithm converged.	0,58	1,26
	AXILLARY PAIN	USA/Canada	262	14,7	9	3,4	252	13,8	7	2,8	1,25		Algorithm converged.	0,46	3,40	0,007		Algorithm converged.	-0,023	0,037	1,24		Algorithm converged.	0,47	3,27	0,6686	-	0,81		Algorithm converged.	0,31	2,14
		Western Europe	814	45,7	13	1,6	824	45,2	13	1,6	1,01		Algorithm converged.	0,47	2,20	0,000		Algorithm converged.	-0,012	0,012	1,01		Algorithm converged.	0,47	2,17	0,9750		0,99		Algorithm converged.	0,46	2,12
		Asia Pacific	482	27,0	5	1,0	517	28,4	1	0,2	5,41		Algorithm converged.	0,63	46,46	0,008		Algorithm converged.	-0,001	0,018	5,36		Algorithm converged.	0,63	45,74	0,1246		0,19		Algorithm converged.	0,02	1,59
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE BRUISE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE ERYTHEMA	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023		1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008		2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE IRRITATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE OEDEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE PAIN	USA/Canada	262	14,7	4	1,5	252	13,8	6	2,4	0,64		Algorithm converged.	0,18	2,28	-0,009		Algorithm converged.	-0,033	0,015	0,64		Algorithm converged.	0,18	2,25	0,4871	-	1,56		Algorithm converged.	0,45	5,46
		Western Europe	814	45,7	9	1,1	824	45,2	8	1,0	1,14		Algorithm converged.	0,44	2,97	0,001		Algorithm converged.	-0,008	0,011	1,14		Algorithm converged.	0,44	2,94	0,7880		0,88		Algorithm converged.	0,34	2,26
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CATHETER SITE PRURITUS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE RASH	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHEST DISCOMFORT	USA/Canada	262	14,7	4	1,5	252	13,8	8	3,2	0,47		Algorithm converged.	0,14	1,59	-0,016		Algorithm converged.	-0,043	0,010	0,48		Algorithm converged.	0,15	1,58	0,2270	-	2,08		Algorithm converged.	0,63	6,82
		Western Europe	814	45,7	7	0,9	824	45,2	12	1,5	0,59		Algorithm converged.	0,23	1,50	-0,006		Algorithm converged.	-0,016	0,004	0,59		Algorithm converged.	0,23	1,49	0,2654		1,69		Algorithm converged.	0,67	4,28
		Asia Pacific	482	27,0	14	2,9	517	28,4	12	2,3	1,26		Algorithm converged.	0,58	2,75	0,006		Algorithm converged.	-0,014	0,026	1,25		Algorithm converged.	0,58	2,68	0,5636		0,80		Algorithm converged.	0,37	1,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHEST PAIN	USA/Canada	262	14,7	13	5,0	252	13,8	9	3,6	1,41		Algorithm converged.	0,59	3,36	0,014		Algorithm converged.	-0,021	0,049		1,39		Algorithm converged.	0,60	3,19	0,4387	-	0,72		Algorithm converged.	0,31	1,65
		Western Europe	814	45,7	28	3,4	824	45,2	38	4,6	0,74		Algorithm converged.	0,45	1,21	-0,012		Algorithm converged.	-0,031	0,007		0,75		Algorithm converged.	0,46	1,20	0,2298		1,34		Algorithm converged.	0,83	2,16
		Asia Pacific	482	27,0	4	0,8	517	28,4	7	1,4	0,61		Algorithm converged.	0,18	2,10	-0,005		Algorithm converged.	-0,018	0,008		0,61		Algorithm converged.	0,18	2,08	0,4324		1,63		Algorithm converged.	0,48	5,54

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	6	3,3	184	10,1	1	0,5	6,20		Algorithm converged.	0,74	52,05	0,027		Algorithm converged.	-0,001	0,055		6,03		Algorithm converged.	0,73	49,62	0,0946		0,17		Algorithm converged.	0,02	1,36
	CHILLS	USA/Canada	262	14,7	24	9,2	252	13,8	27	10,7	0,84		Algorithm converged.	0,47	1,50	-0,016		Algorithm converged.	-0,067	0,036		0,85		Algorithm converged.	0,51	1,44	0,5563	-	1,17		Algorithm converged.	0,69	1,97
		Western Europe	814	45,7	34	4,2	824	45,2	31	3,8	1,12		Algorithm converged.	0,68	1,83	0,004		Algorithm converged.	-0,015	0,023		1,11		Algorithm converged.	0,69	1,79	0,6674		0,90		Algorithm converged.	0,56	1,45
		Asia Pacific	482	27,0	4	0,8	517	28,4	15	2,9	0,28		Algorithm converged.	0,09	0,85	-0,021		Algorithm converged.	-0,037	-0,004		0,29		Algorithm converged.	0,10	0,86	0,0252		3,50		Algorithm converged.	1,17	10,46

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.532081293 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31
	COMPLICATION ASSOCIATED WITH DEVICE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CREPITATIONS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CRYING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYST	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYST RUPTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ENANTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	EXERCISE TOLERANCE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	FACE OEDEMA	USA/Canada	262	14,7	6	2,3	252	13,8	5	2,0	1,16		Algorithm converged.	0,35	3,84	0,003		Algorithm converged.	-0,022	0,028	1,15		Algorithm converged.	0,36	3,73	0,8108	-	0,87		Algorithm converged.	0,27	2,80
		Western Europe	814	45,7	3	0,4	824	45,2	7	0,8	0,43		Algorithm converged.	0,11	1,68	-0,005		Algorithm converged.	-0,012	0,003	0,43		Algorithm converged.	0,11	1,67	0,2250		2,31		Algorithm converged.	0,60	8,88
		Asia Pacific	482	27,0	15	3,1	517	28,4	19	3,7	0,84		Algorithm converged.	0,42	1,68	-0,006		Algorithm converged.	-0,028	0,017	0,85		Algorithm converged.	0,44	1,65	0,6243		1,18		Algorithm converged.	0,61	2,30
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FACIAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAT NECROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	USA/Canada	262	14,7	219	83,6	252	13,8	205	81,3	1,17		Algorithm converged.	0,74	1,84	0,022		Algorithm converged.	-0,043	0,088	1,03		Algorithm converged.	0,95	1,11	0,5051	0,6462	0,97		Algorithm converged.	0,90	1,05
		Western Europe	814	45,7	393	48,3	824	45,2	361	43,8	1,20		Algorithm converged.	0,99	1,45	0,045		Algorithm converged.	-0,004	0,093	1,10		Algorithm converged.	0,99	1,22	0,0699		0,91		Algorithm converged.	0,82	1,01
		Asia Pacific	482	27,0	184	38,2	517	28,4	175	33,8	1,21		Algorithm converged.	0,93	1,56	0,043		Algorithm converged.	-0,016	0,103	1,13		Algorithm converged.	0,96	1,33	0,1547		0,89		Algorithm converged.	0,75	1,05
		Latin America	42	2,4	8	19,0	45	2,5	11	24,4	0,73		Algorithm converged.	0,26	2,03	-0,054		Algorithm converged.	-0,227	0,119	0,78		Algorithm converged.	0,35	1,75	0,5450		1,28		Algorithm converged.	0,57	2,88
		Other	183	10,3	62	33,9	184	10,1	54	29,3	1,23		Algorithm converged.	0,79	1,92	0,045		Algorithm converged.	-0,050	0,140	1,15		Algorithm converged.	0,85	1,56	0,3514		0,87		Algorithm converged.	0,64	1,17
	FEELING ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEELING COLD	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	8	1,0	824	45,2	8	1,0	1,01		Algorithm converged.	0,38	2,71	0,000		Algorithm converged.	-0,009	0,010	1,01		Algorithm converged.	0,38	2,68	0,9804		0,99		Algorithm converged.	0,37	2,62
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEELING HOT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEELING JITTERY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEELING OF BODY TEMPERATURE CHANGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOREIGN BODY REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAIT DISTURBANCE	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	8	1,0	0,50		Algorithm converged.	0,15	1,68	-0,005		Algorithm converged.	-0,013	0,003	0,51		Algorithm converged.	0,15	1,67	0,2646		1,98		Algorithm converged.	0,60	6,54
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENERALISED OEDEMA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	6	0,7	0,17		Algorithm converged.	0,02	1,40	-0,006		Algorithm converged.	-0,012	0,000	0,17		Algorithm converged.	0,02	1,40	0,0991		5,93		Algorithm converged.	0,72	49,12
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HUNGER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERPYREXIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHERMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	HYPOTHERMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ILL-DEFINED DISORDER	USA/Canada	262	14,7	6	2,3	252	13,8	3	1,2	1,95		Algorithm converged.	0,48	7,86	0,011		Algorithm converged.	-0,012	0,034	1,92		Algorithm converged.	0,49	7,61	0,3511	-	0,52		Algorithm converged.	0,13	2,06
		Western Europe	814	45,7	4	0,5	824	45,2	4	0,5	1,01		Algorithm converged.	0,25	4,06	0,000		Algorithm converged.	-0,007	0,007	1,01		Algorithm converged.	0,25	4,03	0,9862		0,99		Algorithm converged.	0,25	3,94
		Asia Pacific	482	27,0	5	1,0	517	28,4	7	1,4	0,76		Algorithm converged.	0,24	2,42	-0,003		Algorithm converged.	-0,017	0,010	0,77		Algorithm converged.	0,24	2,40	0,6472		1,31		Algorithm converged.	0,42	4,08
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	ILLNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644			0,49		Algorithm converged.	0,04	5,44	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055		0,54		Algorithm converged.	0,05	5,69	0,6047			1,87		Algorithm converged.	0,18	19,84	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	IMPAIRED HEALING	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-		2,08		Algorithm converged.	0,19	22,79	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IMPLANT SITE INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INDURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA LIKE ILLNESS	USA/Canada	262	14,7	13	5,0	252	13,8	14	5,6	0,89		Algorithm converged.	0,41	1,93	-0,006		Algorithm converged.	-0,045	0,033	0,89		Algorithm converged.	0,43	1,86	0,7631	-	1,12		Algorithm converged.	0,54	2,33
		Western Europe	814	45,7	46	5,7	824	45,2	41	5,0	1,14		Algorithm converged.	0,74	1,76	0,007		Algorithm converged.	-0,015	0,028	1,14		Algorithm converged.	0,75	1,71	0,5426		0,88		Algorithm converged.	0,58	1,33
		Asia Pacific	482	27,0	37	7,7	517	28,4	31	6,0	1,30		Algorithm converged.	0,80	2,14	0,017		Algorithm converged.	-0,015	0,048	1,28		Algorithm converged.	0,81	2,03	0,2934		0,78		Algorithm converged.	0,49	1,24
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	3	1,6	184	10,1	5	2,7	0,60		Algorithm converged.	0,14	2,53	-0,011		Algorithm converged.	-0,041	0,019		0,60		Algorithm converged.	0,15	2,49	0,4844		1,66		Algorithm converged.	0,40	6,83
	INFUSION SITE EXTRAVASATION	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007		0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012		1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE BRUISING	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INJECTION SITE HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INJECTION SITE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE PHLEBITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INJECTION SITE RASH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE REACTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	6	1,2	517	28,4	5	1,0	1,29		Algorithm converged.	0,39	4,26	0,003		Algorithm converged.	-0,010	0,016	1,29		Algorithm converged.	0,40	4,19	0,6751		0,78		Algorithm converged.	0,24	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOCALISED OEDEMA	USA/Canada	262	14,7	7	2,7	252	13,8	8	3,2	0,84		Algorithm converged.	0,30	2,34	-0,005		Algorithm converged.	-0,034	0,024	0,84		Algorithm converged.	0,31	2,29	0,7353	-	1,19		Algorithm converged.	0,44	3,23
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2	4,32		Algorithm converged.	0,48	38,77	0,006		Algorithm converged.	-0,003	0,015	4,29		Algorithm converged.	0,48	38,25	0,1920		0,23		Algorithm converged.	0,03	2,08
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	USA/Canada	262	14,7	5	1,9	252	13,8	7	2,8	0,68		Algorithm converged.	0,21	2,17	-0,009		Algorithm converged.	-0,035	0,018	0,69		Algorithm converged.	0,22	2,14	0,5167	-	1,46		Algorithm converged.	0,47	4,53
		Western Europe	814	45,7	8	1,0	824	45,2	16	1,9	0,50		Algorithm converged.	0,21	1,18	-0,010		Algorithm converged.	-0,021	0,002	0,51		Algorithm converged.	0,22	1,18	0,1134		1,98		Algorithm converged.	0,85	4,59
		Asia Pacific	482	27,0	41	8,5	517	28,4	48	9,3	0,91		Algorithm converged.	0,59	1,41	-0,008		Algorithm converged.	-0,043	0,028	0,92		Algorithm converged.	0,62	1,36	0,6664		1,09		Algorithm converged.	0,73	1,62
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MEDICAL DEVICE PAIN	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAPLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUCOSAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DRYNESS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	27	3,3	824	45,2	16	1,9	1,73		Algorithm converged.	0,93	3,24	0,014		Algorithm converged.	-0,002	0,029	1,71		Algorithm converged.	0,93	3,15	0,0857		0,59		Algorithm converged.	0,32	1,08
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	5	2,7	0,60		Algorithm converged.	0,14	2,53	-0,011		Algorithm converged.	-0,041	0,019	0,60		Algorithm converged.	0,15	2,49	0,4844		1,66		Algorithm converged.	0,40	6,83
	MUCOSAL HAEMORRHAGE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUCOSAL INFLAMMATION	USA/Canada	262	14,7	85	32,4	252	13,8	49	19,4	1,99		Algorithm converged.	1,33	2,98	0,130		Algorithm converged.	0,055	0,205	1,67		Algorithm converged.	1,23	2,27	0,0010	0,2702	0,60		Algorithm converged.	0,44	0,81
		Western Europe	814	45,7	256	31,4	824	45,2	221	26,8	1,25		Algorithm converged.	1,01	1,55	0,046		Algorithm converged.	0,002	0,090	1,17		Algorithm converged.	1,01	1,36	0,0396		0,85		Algorithm converged.	0,73	0,99
		Asia Pacific	482	27,0	42	8,7	517	28,4	30	5,8	1,55		Algorithm converged.	0,95	2,52	0,029		Algorithm converged.	-0,003	0,061	1,50		Algorithm converged.	0,96	2,36	0,0778		0,67		Algorithm converged.	0,42	1,05
		Latin America	42	2,4	11	26,2	45	2,5	7	15,6	1,93		Algorithm converged.	0,67	5,56	0,106		Algorithm converged.	-0,064	0,276	1,68		Algorithm converged.	0,72	3,94	0,2292		0,59		Algorithm converged.	0,25	1,39
		Other	183	10,3	11	6,0	184	10,1	8	4,3	1,41		Algorithm converged.	0,55	3,58	0,017		Algorithm converged.	-0,029	0,062	1,38		Algorithm converged.	0,57	3,36	0,4744		0,72		Algorithm converged.	0,30	1,76
	MUCOSAL TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NODULE	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NON-CARDIAC CHEST PAIN	USA/Canada	262	14,7	4	1,5	252	13,8	11	4,4	0,34		Algorithm converged.	0,11	1,08	-0,028		Algorithm converged.	-0,058	0,001	0,35		Algorithm converged.	0,11	1,08	0,0687	-	2,86		Algorithm converged.	0,92	8,86
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA	USA/Canada	262	14,7	10	3,8	252	13,8	16	6,3	0,59		Algorithm converged.	0,26	1,32	-0,025		Algorithm converged.	-0,063	0,013	0,60		Algorithm converged.	0,28	1,30	0,1957	-	1,66		Algorithm converged.	0,77	3,60
		Western Europe	814	45,7	55	6,8	824	45,2	52	6,3	1,08		Algorithm converged.	0,73	1,59	0,004		Algorithm converged.	-0,019	0,028	1,07		Algorithm converged.	0,74	1,54	0,7149		0,93		Algorithm converged.	0,65	1,35
		Asia Pacific	482	27,0	45	9,3	517	28,4	44	8,5	1,11		Algorithm converged.	0,72	1,71	0,008		Algorithm converged.	-0,027	0,044	1,10		Algorithm converged.	0,74	1,63	0,6473		0,91		Algorithm converged.	0,61	1,36
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	5	2,7	0,20		Algorithm converged.	0,02	1,70	-0,022		Algorithm converged.	-0,048	0,004	0,20		Algorithm converged.	0,02	1,70	0,1413		4,97		Algorithm converged.	0,59	42,15
	OEDEMA PERIPHERAL	USA/Canada	262	14,7	63	24,0	252	13,8	86	34,1	0,61		Algorithm converged.	0,42	0,90	-0,101		Algorithm converged.	-0,179	-0,023	0,70		Algorithm converged.	0,54	0,93	0,0126	-	1,42		Algorithm converged.	1,08	1,87
		Western Europe	814	45,7	117	14,4	824	45,2	149	18,1	0,76		Algorithm converged.	0,58	0,99	-0,037		Algorithm converged.	-0,073	-0,001	0,79		Algorithm converged.	0,64	0,99	0,0426		1,26		Algorithm converged.	1,01	1,57
		Asia Pacific	482	27,0	99	20,5	517	28,4	110	21,3	0,96		Algorithm converged.	0,70	1,30	-0,007		Algorithm converged.	-0,058	0,043	0,97		Algorithm converged.	0,76	1,23	0,7747		1,04		Algorithm converged.	0,81	1,32
		Latin America	42	2,4	4	9,5	45	2,5	4	8,9	1,08		Algorithm converged.	0,25	4,62	0,006		Algorithm converged.	-0,115	0,128	1,07		Algorithm converged.	0,29	4,01	0,9184		0,93		Algorithm converged.	0,25	3,50
		Other	183	10,3	21	11,5	184	10,1	19	10,3	1,13		Algorithm converged.	0,58	2,17	0,011		Algorithm converged.	-0,052	0,075	1,11		Algorithm converged.	0,62	2,00	0,7240		0,90		Algorithm converged.	0,50	1,62
	PAIN	USA/Canada	262	14,7	27	10,3	252	13,8	24	9,5	1,09		Algorithm converged.	0,61	1,95	0,008		Algorithm converged.	-0,044	0,059	1,08		Algorithm converged.	0,64	1,82	0,7671	-	0,92		Algorithm converged.	0,55	1,56
		Western Europe	814	45,7	68	8,4	824	45,2	58	7,0	1,20		Algorithm converged.	0,84	1,73	0,013		Algorithm converged.	-0,013	0,039	1,19		Algorithm converged.	0,85	1,66	0,3187		0,84		Algorithm converged.	0,60	1,18
		Asia Pacific	482	27,0	25	5,2	517	28,4	28	5,4	0,96		Algorithm converged.	0,55	1,66	-0,002		Algorithm converged.	-0,030	0,026	0,96		Algorithm converged.	0,57	1,62	0,8717		1,04		Algorithm converged.	0,62	1,76
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055	0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	5	2,7	184	10,1	2	1,1	2,56		Algorithm converged.	0,49	13,35	0,016		Algorithm converged.	-0,012	0,044	2,51		Algorithm converged.	0,49	12,79	0,2668		0,40		Algorithm converged.	0,08	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL SWELLING	USA/Canada	262	14,7	5	1,9	252	13,8	11	4,4	0,43		Algorithm converged.	0,15	1,24	-0,025		Algorithm converged.	-0,055	0,006	0,44		Algorithm converged.	0,15	1,24	0,1200	-	2,29		Algorithm converged.	0,81	6,49
		Western Europe	814	45,7	16	2,0	824	45,2	12	1,5	1,36		Algorithm converged.	0,64	2,89	0,005		Algorithm converged.	-0,007	0,018	1,35		Algorithm converged.	0,64	2,84	0,4284		0,74		Algorithm converged.	0,35	1,56
		Asia Pacific	482	27,0	6	1,2	517	28,4	9	1,7	0,71		Algorithm converged.	0,25	2,01	-0,005		Algorithm converged.	-0,020	0,010	0,72		Algorithm converged.	0,26	1,99	0,5216		1,40		Algorithm converged.	0,50	3,90
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92
	PUNCTURE SITE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYREXIA	USA/Canada	262	14,7	49	18,7	252	13,8	52	20,6	0,88		Algorithm converged.	0,57	1,37	-0,019		Algorithm converged.	-0,088	0,049	0,91		Algorithm converged.	0,64	1,29	0,5816	-	1,10		Algorithm converged.	0,78	1,57
		Western Europe	814	45,7	182	22,4	824	45,2	169	20,5	1,12		Algorithm converged.	0,88	1,41	0,018		Algorithm converged.	-0,021	0,058	1,09		Algorithm converged.	0,91	1,31	0,3621		0,92		Algorithm converged.	0,76	1,10
		Asia Pacific	482	27,0	112	23,2	517	28,4	111	21,5	1,11		Algorithm converged.	0,82	1,49	0,018		Algorithm converged.	-0,034	0,069	1,08		Algorithm converged.	0,86	1,36	0,5029		0,92		Algorithm converged.	0,73	1,16
		Latin America	42	2,4	4	9,5	45	2,5	2	4,4	2,26		Algorithm converged.	0,39	13,06	0,051		Algorithm converged.	-0,056	0,158	2,14		Algorithm converged.	0,41	11,10	0,3637		0,47		Algorithm converged.	0,09	2,42
		Other	183	10,3	12	6,6	184	10,1	12	6,5	1,01		Algorithm converged.	0,44	2,30	0,000		Algorithm converged.	-0,050	0,051	1,01		Algorithm converged.	0,46	2,18	0,9890		0,99		Algorithm converged.	0,46	2,16
	SCAR INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SECRETION DISCHARGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SENSATION OF FOREIGN BODY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPRAPUBIC PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SWELLING	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SWELLING FACE	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TEMPERATURE INTOLERANCE	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	TEMPERATURE REGULATION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDERNESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THIRST	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	6	1,2	517	28,4	4	0,8	1,62		Algorithm converged.	0,45	5,76	0,005		Algorithm converged.	-0,008	0,017	1,61		Algorithm converged.	0,46	5,67	0,4591		0,62		Algorithm converged.	0,18	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UNEVALUABLE EVENT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	2	1,1	2,03		Algorithm converged.	0,37	11,24	0,011		Algorithm converged.	-0,015	0,037	2,01		Algorithm converged.	0,37	10,84	0,4164		0,50		Algorithm converged.	0,09	2,68
	VASCULAR DEVICE OCCLUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	VESSEL PUNCTURE SITE BRUISE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	XEROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	10	1,2	824	45,2	3	0,4	3,40		Algorithm converged.	0,93	12,41	0,009		Algorithm converged.	0,000	0,017		3,37		Algorithm converged.	0,93	12,22	0,0639		0,30		Algorithm converged.	0,08	1,07	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	13	1,6	824	45,2	15	1,8	0,88		Algorithm converged.	0,41	1,85	-0,002		Algorithm converged.	-0,015	0,010	0,88		Algorithm converged.	0,42	1,83	0,7275		1,14		Algorithm converged.	0,55	2,38
		Asia Pacific	482	27,0	33	6,8	517	28,4	38	7,4	0,93		Algorithm converged.	0,57	1,50	-0,005		Algorithm converged.	-0,037	0,027	0,93		Algorithm converged.	0,59	1,46	0,7570		1,07		Algorithm converged.	0,68	1,68
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92
	BILIARY COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLECYSTITIS CHRONIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98	
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CHOLESTASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DRUG-INDUCED LIVER INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	GALLBLADDER POLYP	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013		1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,004		Algorithm converged.	-0,010	0,003		0,40		Algorithm converged.	0,08	2,08	0,2790		2,47		Algorithm converged.	0,48	12,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC FUNCTION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	11	2,3	517	28,4	21	4,1	0,55		Algorithm converged.	0,26	1,16	-0,018		Algorithm converged.	-0,039	0,004		0,56		Algorithm converged.	0,27	1,15	0,1160		1,78		Algorithm converged.	0,87	3,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC STEATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	9	1,9	517	28,4	8	1,5	1,21		Algorithm converged.	0,46	3,16	0,003		Algorithm converged.	-0,013	0,019	1,21		Algorithm converged.	0,47	3,10	0,6965		0,83		Algorithm converged.	0,32	2,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	HEPATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATOBILIARY DISEASE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002002 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATOTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERBILIRUBINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERTRANSAMINASAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LIVER DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIVER INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	5	1,0	517	28,4	5	1,0	1,07		Algorithm converged.	0,31	3,73	0,001		Algorithm converged.	-0,012	0,013	1,07		Algorithm converged.	0,31	3,68	0,9113		0,93		Algorithm converged.	0,27	3,20
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR ICTERUS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	19	7,3	252	13,8	16	6,3	1,15		Algorithm converged.	0,58	2,30	0,009		Algorithm converged.	-0,034	0,053	1,14		Algorithm converged.	0,60	2,17	0,6849	-	0,88		Algorithm converged.	0,46	1,66
		Western Europe	814	45,7	39	4,8	824	45,2	35	4,2	1,13		Algorithm converged.	0,71	1,81	0,005		Algorithm converged.	-0,015	0,026	1,13		Algorithm converged.	0,72	1,76	0,5966		0,89		Algorithm converged.	0,57	1,38
		Asia Pacific	482	27,0	29	6,0	517	28,4	18	3,5	1,77		Algorithm converged.	0,97	3,24	0,025		Algorithm converged.	-0,001	0,052	1,73		Algorithm converged.	0,97	3,07	0,0622		0,58		Algorithm converged.	0,33	1,03
		Latin America	42	2,4	3	7,1	45	2,5	6	13,3	0,50		Algorithm converged.	0,12	2,14	-0,062		Algorithm converged.	-0,188	0,064	0,54		Algorithm converged.	0,14	2,01	0,3543		1,87		Algorithm converged.	0,50	6,99
		Other	183	10,3	9	4,9	184	10,1	5	2,7	1,85		Algorithm converged.	0,61	5,64	0,022		Algorithm converged.	-0,017	0,061	1,81		Algorithm converged.	0,62	5,30	0,2789		0,55		Algorithm converged.	0,19	1,62
	ALLERGIC OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLERGY TO ANIMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DECREASED IMMUNE RESPONSIVENESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	9	3,4	252	13,8	3	1,2	2,95		Algorithm converged.	0,79	11,03	0,022		Algorithm converged.	-0,003	0,048		2,89		Algorithm converged.	0,79	10,54	0,1088	-	0,35		Algorithm converged.	0,09	1,27
		Western Europe	814	45,7	9	1,1	824	45,2	4	0,5	2,29		Algorithm converged.	0,70	7,47	0,006		Algorithm converged.	-0,002	0,015		2,28		Algorithm converged.	0,70	7,37	0,1693		0,44		Algorithm converged.	0,14	1,42
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	3	1,6	1,01		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,026	0,026		1,01		Algorithm converged.	0,21	4,92	0,9946		0,99		Algorithm converged.	0,20	4,86
	FOOD ALLERGY	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	USA/Canada	262	14,7	6	2,3	252	13,8	7	2,8	0,82		Algorithm converged.	0,27	2,48	-0,005		Algorithm converged.	-0,032	0,022	0,82		Algorithm converged.	0,28	2,42	0,7252	-	1,21		Algorithm converged.	0,41	3,56
		Western Europe	814	45,7	22	2,7	824	45,2	24	2,9	0,93		Algorithm converged.	0,51	1,67	-0,002		Algorithm converged.	-0,018	0,014	0,93		Algorithm converged.	0,52	1,64	0,7971		1,08		Algorithm converged.	0,61	1,91
		Asia Pacific	482	27,0	18	3,7	517	28,4	14	2,7	1,39		Algorithm converged.	0,69	2,83	0,010		Algorithm converged.	-0,012	0,032	1,38		Algorithm converged.	0,69	2,74	0,3594		0,73		Algorithm converged.	0,36	1,44
		Latin America	42	2,4	2	4,8	45	2,5	5	11,1	0,40		Algorithm converged.	0,07	2,18	-0,063		Algorithm converged.	-0,176	0,049	0,43		Algorithm converged.	0,09	2,09	0,2948		2,33		Algorithm converged.	0,48	11,38
		Other	183	10,3	5	2,7	184	10,1	2	1,1	2,56		Algorithm converged.	0,49	13,35	0,016		Algorithm converged.	-0,012	0,044	2,51		Algorithm converged.	0,49	12,79	0,2668		0,40		Algorithm converged.	0,08	2,02
	IMMUNE SYSTEM DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED HYPERSENSITIVITY REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEASONAL ALLERGY	USA/Canada	262	14,7	3	1,1	252	13,8	5	2,0	0,57		Algorithm converged.	0,14	2,42	-0,008		Algorithm converged.	-0,030	0,013	0,58		Algorithm converged.	0,14	2,39	0,4483	-	1,73		Algorithm converged.	0,42	7,18
		Western Europe	814	45,7	8	1,0	824	45,2	1	0,1	8,17		Algorithm converged.	1,02	65,46	0,009		Algorithm converged.	0,001	0,016	8,10		Algorithm converged.	1,02	64,60	0,0484		0,12		Algorithm converged.	0,02	0,99
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERUM SICKNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	172	65,6	252	13,8	169	67,1	0,94		Algorithm converged.	0,65	1,35	-0,014		Algorithm converged.	-0,096	0,068	0,98		Algorithm converged.	0,87	1,11	0,7343	0,5513	1,02		Algorithm converged.	0,90	1,16
		Western Europe	814	45,7	535	65,7	824	45,2	521	63,2	1,12		Algorithm converged.	0,91	1,37	0,025		Algorithm converged.	-0,021	0,071	1,04		Algorithm converged.	0,97	1,12	0,2912		0,96		Algorithm converged.	0,90	1,03
		Asia Pacific	482	27,0	265	55,0	517	28,4	269	52,0	1,13		Algorithm converged.	0,88	1,44	0,029		Algorithm converged.	-0,032	0,091	1,06		Algorithm converged.	0,94	1,19	0,3503		0,95		Algorithm converged.	0,84	1,06
		Latin America	42	2,4	24	57,1	45	2,5	19	42,2	1,82		Algorithm converged.	0,78	4,27	0,149		Algorithm converged.	-0,059	0,357	1,35		Algorithm converged.	0,88	2,08	0,1684		0,74		Algorithm converged.	0,48	1,14
		Other	183	10,3	88	48,1	184	10,1	78	42,4	1,26		Algorithm converged.	0,83	1,90	0,057		Algorithm converged.	-0,045	0,159	1,13		Algorithm converged.	0,90	1,42	0,2740		0,88		Algorithm converged.	0,70	1,10

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS JAW	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS LIMB	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABSCESS ORAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ACARODERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACTINOMYCOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE SINUSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ADENOVIRAL CONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FUNGAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARTHRITIS INFECTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASCARIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BACTERIAL VAGINOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BACTERIAL VULVOVAGINITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BARTHOLINITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BETA HAEMOLYTIC STREPTOCOCCAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BODY TINEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BOTRYOMYCOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BRONCHIOLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	USA/Canada	262	14,7	5	1,9	252	13,8	7	2,8	0,68		Algorithm converged.	0,21	2,17	-0,009		Algorithm converged.	-0,035	0,018		0,69		Algorithm converged.	0,22	2,14	0,5167	-	1,46		Algorithm converged.	0,47	4,53
		Western Europe	814	45,7	38	4,7	824	45,2	45	5,5	0,85		Algorithm converged.	0,54	1,32	-0,008		Algorithm converged.	-0,029	0,013		0,85		Algorithm converged.	0,56	1,30	0,4650		1,17		Algorithm converged.	0,77	1,78
		Asia Pacific	482	27,0	4	0,8	517	28,4	12	2,3	0,35		Algorithm converged.	0,11	1,10	-0,015		Algorithm converged.	-0,030	0,000		0,36		Algorithm converged.	0,12	1,10	0,0731		2,80		Algorithm converged.	0,91	8,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	7	3,8	184	10,1	7	3,8	1,01		Algorithm converged.	0,35	2,93	0,000		Algorithm converged.	-0,039	0,039	1,01		Algorithm converged.	0,36	2,81	0,9917		0,99		Algorithm converged.	0,36	2,78
	BRONCHITIS VIRAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BULLOUS IMPETIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURN INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CAMPYLOBACTER INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CANDIDA INFECTION	USA/Canada	262	14,7	12	4,6	252	13,8	12	4,8	0,96		Algorithm converged.	0,42	2,18	-0,002		Algorithm converged.	-0,038	0,035	0,96		Algorithm converged.	0,44	2,10	0,9222	-	1,04		Algorithm converged.	0,48	2,27
		Western Europe	814	45,7	10	1,2	824	45,2	6	0,7	1,70		Algorithm converged.	0,61	4,69	0,005		Algorithm converged.	-0,005	0,015	1,69		Algorithm converged.	0,62	4,62	0,3089		0,59		Algorithm converged.	0,22	1,62
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARBUNCLE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006		1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE PUSTULE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	USA/Canada	262	14,7	10	3,8	252	13,8	13	5,2	0,73		Algorithm converged.	0,31	1,70	-0,013		Algorithm converged.	-0,049	0,022	0,74		Algorithm converged.	0,33	1,66	0,4638	-	1,35		Algorithm converged.	0,60	3,03
		Western Europe	814	45,7	10	1,2	824	45,2	8	1,0	1,27		Algorithm converged.	0,50	3,23	0,003		Algorithm converged.	-0,008	0,013	1,27		Algorithm converged.	0,50	3,19	0,6179		0,79		Algorithm converged.	0,31	1,99
		Asia Pacific	482	27,0	11	2,3	517	28,4	9	1,7	1,32		Algorithm converged.	0,54	3,21	0,005		Algorithm converged.	-0,012	0,023	1,31		Algorithm converged.	0,55	3,14	0,5429		0,76		Algorithm converged.	0,32	1,82
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	CELLULITIS ORBITAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CERVICITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHEST WALL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC SINUSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC TONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE COLITIS	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	USA/Canada	262	14,7	5	1,9	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVITIS	USA/Canada	262	14,7	7	2,7	252	13,8	4	1,6	1,70		Algorithm converged.	0,49	5,89	0,011		Algorithm converged.	-0,014	0,036	1,68		Algorithm converged.	0,50	5,68	0,4014	-	0,59		Algorithm converged.	0,18	2,00
		Western Europe	814	45,7	82	10,1	824	45,2	67	8,1	1,27		Algorithm converged.	0,90	1,78	0,019		Algorithm converged.	-0,008	0,047	1,24		Algorithm converged.	0,91	1,69	0,1726		0,81		Algorithm converged.	0,59	1,10
		Asia Pacific	482	27,0	13	2,7	517	28,4	15	2,9	0,93		Algorithm converged.	0,44	1,97	-0,002		Algorithm converged.	-0,022	0,018	0,93		Algorithm converged.	0,45	1,93	0,8451		1,08		Algorithm converged.	0,52	2,24
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	5	2,7	184	10,1	5	2,7	1,01		Algorithm converged.	0,29	3,53	0,000		Algorithm converged.	-0,033	0,033	1,01		Algorithm converged.	0,30	3,41	0,9930		0,99		Algorithm converged.	0,29	3,38
	CONJUNCTIVITIS VIRAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE
	CYSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	39	4,8	824	45,2	31	3,8	1,29		Algorithm converged.	0,80	2,08	0,010		Algorithm converged.	-0,009	0,030	1,27		Algorithm converged.	0,80	2,02	0,3046		0,79		Algorithm converged.	0,49	1,25
		Asia Pacific	482	27,0	17	3,5	517	28,4	11	2,1	1,68		Algorithm converged.	0,78	3,63	0,014		Algorithm converged.	-0,007	0,035	1,66		Algorithm converged.	0,78	3,50	0,1855		0,60		Algorithm converged.	0,29	1,27
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	7	3,8	184	10,1	5	2,7	1,42		Algorithm converged.	0,44	4,57	0,011		Algorithm converged.	-0,025	0,047	1,41		Algorithm converged.	0,46	4,35	0,5529		0,71		Algorithm converged.	0,23	2,20
	DENGUE FEVER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS INFECTED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATOPHYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011	1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	DIARRHOEA INFECTIOUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE		NE				
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326			0,47		Algorithm converged.	0,04	5,12						
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE				
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIENTAMOEBA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISSEMINATED TUBERCULOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS INTESTINAL PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EAR INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,004		Algorithm converged.	-0,011	0,004	0,58		Algorithm converged.	0,17	1,97	0,3810		1,73		Algorithm converged.	0,51	5,88
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ENDOCARDITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ENTERITIS INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ENTEROBIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	11	1,4	824	45,2	6	0,7	1,87		Algorithm converged.	0,69	5,07	0,006		Algorithm converged.	-0,004	0,016	1,86		Algorithm converged.	0,69	4,99	0,2209		0,54		Algorithm converged.	0,20	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	5	2,7	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ESCHERICHIA URINARY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EYE INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	5	2,0	0,19		Algorithm converged.	0,02	1,63	-0,016		Algorithm converged.	-0,035	0,003		0,19		Algorithm converged.	0,02	1,64	0,1311	-	5,20		Algorithm converged.	0,61	44,19
		Western Europe	814	45,7	8	1,0	824	45,2	11	1,3	0,73		Algorithm converged.	0,29	1,83	-0,004		Algorithm converged.	-0,014	0,007		0,74		Algorithm converged.	0,30	1,82	0,5074		1,36		Algorithm converged.	0,55	3,36
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	EYELID FOLLICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOLLICULITIS	USA/Canada	262	14,7	3	1,1	252	13,8	6	2,4	0,47		Algorithm converged.	0,12	1,92	-0,012		Algorithm converged.	-0,035	0,010	0,48		Algorithm converged.	0,12	1,90	0,2967	-	2,08		Algorithm converged.	0,53	8,22
		Western Europe	814	45,7	15	1,8	824	45,2	4	0,5	3,85		Algorithm converged.	1,27	11,65	0,014		Algorithm converged.	0,003	0,024	3,80		Algorithm converged.	1,27	11,39	0,0173		0,26		Algorithm converged.	0,09	0,79
		Asia Pacific	482	27,0	8	1,7	517	28,4	4	0,8	2,16		Algorithm converged.	0,65	7,23	0,009		Algorithm converged.	-0,005	0,023	2,15		Algorithm converged.	0,65	7,08	0,2102		0,47		Algorithm converged.	0,14	1,54
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNGAL INFECTION	USA/Canada	262	14,7	5	1,9	252	13,8	5	2,0	0,96		Algorithm converged.	0,27	3,36	-0,001		Algorithm converged.	-0,025	0,023	0,96		Algorithm converged.	0,28	3,28	0,9505	-	1,04		Algorithm converged.	0,30	3,55
		Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011	1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNGAL OESOPHAGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNGAL PHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FUNGAL SKIN INFECTION	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028		3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	6	0,7	824	45,2	6	0,7	1,01		Algorithm converged.	0,33	3,15	0,000		Algorithm converged.	-0,008	0,008		1,01		Algorithm converged.	0,33	3,13	0,9831		0,99		Algorithm converged.	0,32	3,05
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013		0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	FURUNCLE	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010		0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6	0,61		Algorithm converged.	0,14	2,54	-0,002		Algorithm converged.	-0,009	0,004		0,61		Algorithm converged.	0,15	2,53	0,4938		1,65		Algorithm converged.	0,39	6,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	26	3,2	824	45,2	22	2,7	1,20		Algorithm converged.	0,68	2,14	0,005		Algorithm converged.	-0,011	0,022		1,20		Algorithm converged.	0,68	2,09	0,5300		0,84		Algorithm converged.	0,48	1,46
		Asia Pacific	482	27,0	4	0,8	517	28,4	9	1,7	0,47		Algorithm converged.	0,14	1,54	-0,009		Algorithm converged.	-0,023	0,005		0,48		Algorithm converged.	0,15	1,54	0,2151		2,10		Algorithm converged.	0,65	6,77
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROENTERITIS VIRAL	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015		0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	GASTROINTESTINAL FUNGAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENITAL HERPES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	GENITAL HERPES SIMPLEX	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	GENITAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	GENITAL INFECTION FEMALE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GENITAL INFECTION FUNGAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GENITOURINARY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	8	1,0	824	45,2	11	1,3	0,73		Algorithm converged.	0,29	1,83	-0,004		Algorithm converged.	-0,014	0,007	0,74		Algorithm converged.	0,30	1,82	0,5074		1,36		Algorithm converged.	0,55	3,36
		Asia Pacific	482	27,0	16	3,3	517	28,4	14	2,7	1,23		Algorithm converged.	0,60	2,56	0,006		Algorithm converged.	-0,015	0,027	1,23		Algorithm converged.	0,60	2,48	0,5721		0,82		Algorithm converged.	0,40	1,65
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	3	1,6	0,33		Algorithm converged.	0,03	3,22	-0,011		Algorithm converged.	-0,032	0,010	0,34		Algorithm converged.	0,04	3,19	0,3418		2,98		Algorithm converged.	0,31	28,42
	GROIN ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	H1N1 INFLUENZA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HELICOBACTER INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS B REACTIVATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	HERPES OPHTHALMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES SIMPLEX	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	5	0,6	824	45,2	6	0,7	0,84		Algorithm converged.	0,26	2,77	-0,001		Algorithm converged.	-0,009	0,007	0,84		Algorithm converged.	0,26	2,75	0,7780		1,19		Algorithm converged.	0,36	3,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HERPES VIRUS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	12	1,5	824	45,2	6	0,7	2,04		Algorithm converged.	0,76	5,46	0,007		Algorithm converged.	-0,003	0,018	2,02		Algorithm converged.	0,76	5,37	0,1563		0,49		Algorithm converged.	0,19	1,31
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES ZOSTER	USA/Canada	262	14,7	5	1,9	252	13,8	5	2,0	0,96		Algorithm converged.	0,27	3,36	-0,001		Algorithm converged.	-0,025	0,023	0,96		Algorithm converged.	0,28	3,28	0,9505	-	1,04		Algorithm converged.	0,30	3,55
		Western Europe	814	45,7	18	2,2	824	45,2	17	2,1	1,07		Algorithm converged.	0,55	2,10	0,001		Algorithm converged.	-0,013	0,015	1,07		Algorithm converged.	0,56	2,06	0,8357		0,93		Algorithm converged.	0,48	1,80
		Asia Pacific	482	27,0	11	2,3	517	28,4	22	4,3	0,53		Algorithm converged.	0,25	1,10	-0,020		Algorithm converged.	-0,042	0,002	0,54		Algorithm converged.	0,26	1,09	0,0868		1,86		Algorithm converged.	0,91	3,80
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	5	2,7	0,40		Algorithm converged.	0,08	2,07	-0,016		Algorithm converged.	-0,044	0,012	0,40		Algorithm converged.	0,08	2,05	0,2725		2,49		Algorithm converged.	0,49	12,65
	HORDEOLUM	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033	1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	3	0,4	824	45,2	8	1,0	0,38		Algorithm converged.	0,10	1,43	-0,006		Algorithm converged.	-0,014	0,002	0,38		Algorithm converged.	0,10	1,43	0,1514		2,63		Algorithm converged.	0,70	9,89
		Asia Pacific	482	27,0	5	1,0	517	28,4	6	1,2	0,89		Algorithm converged.	0,27	2,94	-0,001		Algorithm converged.	-0,014	0,012	0,89		Algorithm converged.	0,27	2,91	0,8522		1,12		Algorithm converged.	0,34	3,64
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	IMPETIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE CELLULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED BITE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTED SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017		1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	28	3,4	824	45,2	26	3,2	1,09		Algorithm converged.	0,64	1,88	0,003		Algorithm converged.	-0,014	0,020		1,09		Algorithm converged.	0,64	1,84	0,7472		0,92		Algorithm converged.	0,54	1,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	4	0,8	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	0,031	*	WARNING: The relative Hessian convergence criterion of 18.885863102 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,121	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA	USA/Canada	262	14,7	5	1,9	252	13,8	7	2,8	0,68		Algorithm converged.	0,21	2,17	-0,009		Algorithm converged.	-0,035	0,018	0,69		Algorithm converged.	0,22	2,14	0,5167	-	1,46		Algorithm converged.	0,47	4,53
		Western Europe	814	45,7	27	3,3	824	45,2	29	3,5	0,94		Algorithm converged.	0,55	1,60	-0,002		Algorithm converged.	-0,020	0,016	0,94		Algorithm converged.	0,56	1,58	0,8216		1,06		Algorithm converged.	0,63	1,78
		Asia Pacific	482	27,0	3	0,6	517	28,4	10	1,9	0,32		Algorithm converged.	0,09	1,16	-0,013		Algorithm converged.	-0,027	0,001	0,32		Algorithm converged.	0,09	1,16	0,0835		3,11		Algorithm converged.	0,86	11,22
		Latin America	42	2,4	2	4,8	45	2,5	3	6,7	0,70		Algorithm converged.	0,11	4,41	-0,019		Algorithm converged.	-0,116	0,078	0,71		Algorithm converged.	0,13	4,07	0,7045		1,40		Algorithm converged.	0,25	7,97
		Other	183	10,3	8	4,4	184	10,1	12	6,5	0,66		Algorithm converged.	0,26	1,64	-0,022		Algorithm converged.	-0,068	0,025	0,67		Algorithm converged.	0,28	1,60	0,3680		1,49		Algorithm converged.	0,62	3,56
	LABYRINTHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGITIS	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	8	1,0	824	45,2	11	1,3	0,73		Algorithm converged.	0,29	1,83	-0,004		Algorithm converged.	-0,014	0,007	0,74		Algorithm converged.	0,30	1,82	0,5074		1,36		Algorithm converged.	0,55	3,36
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LARYNGOPHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIP INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	4	0,5	1,01		Algorithm converged.	0,25	4,06	0,000		Algorithm converged.	-0,007	0,007	1,01		Algorithm converged.	0,25	4,03	0,9862		0,99		Algorithm converged.	0,25	3,94
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	LOCALISED INFECTION	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	10	1,2	824	45,2	7	0,8	1,45		Algorithm converged.	0,55	3,83	0,004		Algorithm converged.	-0,006	0,014	1,45		Algorithm converged.	0,55	3,78	0,4519		0,69		Algorithm converged.	0,26	1,81
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	16	2,0	824	45,2	11	1,3	1,48		Algorithm converged.	0,68	3,21	0,006		Algorithm converged.	-0,006	0,019	1,47		Algorithm converged.	0,69	3,15	0,3194		0,68		Algorithm converged.	0,32	1,45
		Asia Pacific	482	27,0	1	0,2	517	28,4	4	0,8	0,27		Algorithm converged.	0,03	2,39	-0,006		Algorithm converged.	-0,014	0,003	0,27		Algorithm converged.	0,03	2,39	0,2383		3,73		Algorithm converged.	0,42	33,25
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPH GLAND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MASTITIS	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023	1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	15	1,8	824	45,2	15	1,8	1,01		Algorithm converged.	0,49	2,08	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,50	2,06	0,9731		0,99		Algorithm converged.	0,49	2,01
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MORAXELLA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MUCOSAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MUMPS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	MYCOBACTERIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	MYRINGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL BED INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	8	3,2	0,23		Algorithm converged.	0,05	1,12	-0,024		Algorithm converged.	-0,048	0,000	0,24		Algorithm converged.	0,05	1,12	0,0697	-	4,16		Algorithm converged.	0,89	19,40

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	16	2,0	824	45,2	10	1,2	1,63		Algorithm converged.	0,74	3,62	0,008		Algorithm converged.	-0,005	0,020	1,62		Algorithm converged.	0,74	3,55	0,2281		0,62		Algorithm converged.	0,28	1,35
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002002 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	NASAL HERPES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL VESTIBULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASOPHARYNGITIS	USA/Canada	262	14,7	14	5,3	252	13,8	13	5,2	1,04		Algorithm converged.	0,48	2,25	0,002		Algorithm converged.	-0,037	0,040	1,04		Algorithm converged.	0,50	2,16	0,9252	-	0,97		Algorithm converged.	0,46	2,01
		Western Europe	814	45,7	117	14,4	824	45,2	105	12,7	1,15		Algorithm converged.	0,87	1,53	0,016		Algorithm converged.	-0,017	0,049	1,13		Algorithm converged.	0,88	1,44	0,3354		0,89		Algorithm converged.	0,69	1,13
		Asia Pacific	482	27,0	92	19,1	517	28,4	88	17,0	1,15		Algorithm converged.	0,83	1,59	0,021		Algorithm converged.	-0,027	0,068	1,12		Algorithm converged.	0,86	1,46	0,3961		0,89		Algorithm converged.	0,68	1,16
		Latin America	42	2,4	5	11,9	45	2,5	4	8,9	1,39		Algorithm converged.	0,35	5,55	0,030		Algorithm converged.	-0,098	0,159	1,34		Algorithm converged.	0,39	4,65	0,6458		0,75		Algorithm converged.	0,21	2,60
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31
	NEUTROPENIC INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	3	0,4	2,37		Algorithm converged.	0,61	9,21	0,005		Algorithm converged.	-0,003	0,013	2,36		Algorithm converged.	0,61	9,10	0,2118		0,42		Algorithm converged.	0,11	1,63
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OESOPHAGEAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OMPHALITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOMYCOSIS	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL CANDIDIASIS	USA/Canada	262	14,7	8	3,1	252	13,8	10	4,0	0,76		Algorithm converged.	0,30	1,96	-0,009		Algorithm converged.	-0,041	0,023	0,77		Algorithm converged.	0,31	1,92	0,5739	-	1,30		Algorithm converged.	0,52	3,24
		Western Europe	814	45,7	12	1,5	824	45,2	17	2,1	0,71		Algorithm converged.	0,34	1,50	-0,006		Algorithm converged.	-0,019	0,007	0,71		Algorithm converged.	0,34	1,49	0,3686		1,40		Algorithm converged.	0,67	2,91
		Asia Pacific	482	27,0	2	0,4	517	28,4	6	1,2	0,35		Algorithm converged.	0,07	1,77	-0,007		Algorithm converged.	-0,018	0,003	0,36		Algorithm converged.	0,07	1,76	0,2064		2,80		Algorithm converged.	0,57	13,79
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ORAL FUNGAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	9	1,1	824	45,2	6	0,7	1,52		Algorithm converged.	0,54	4,30	0,004		Algorithm converged.	-0,005	0,013	1,52		Algorithm converged.	0,54	4,25	0,4260		0,66		Algorithm converged.	0,24	1,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL HERPES	USA/Canada	262	14,7	5	1,9	252	13,8	6	2,4	0,80		Algorithm converged.	0,24	2,65	-0,005		Algorithm converged.	-0,030	0,020	0,80		Algorithm converged.	0,25	2,59	0,7119	-	1,25		Algorithm converged.	0,39	4,04
		Western Europe	814	45,7	23	2,8	824	45,2	18	2,2	1,30		Algorithm converged.	0,70	2,43	0,006		Algorithm converged.	-0,009	0,022	1,29		Algorithm converged.	0,70	2,38	0,4077		0,77		Algorithm converged.	0,42	1,42
		Asia Pacific	482	27,0	2	0,4	517	28,4	7	1,4	0,30		Algorithm converged.	0,06	1,47	-0,009		Algorithm converged.	-0,021	0,002	0,31		Algorithm converged.	0,06	1,47	0,1390		3,26		Algorithm converged.	0,68	15,63
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS EXTERNA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OTITIS MEDIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLOMA VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARONYCHIA	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	31	3,8	824	45,2	19	2,3	1,68		Algorithm converged.	0,94	2,99	0,015		Algorithm converged.	-0,002	0,032	1,65		Algorithm converged.	0,94	2,90	0,0806		0,61		Algorithm converged.	0,34	1,06
		Asia Pacific	482	27,0	28	5,8	517	28,4	15	2,9	2,06		Algorithm converged.	1,09	3,91	0,029		Algorithm converged.	0,004	0,054	2,00		Algorithm converged.	1,08	3,70	0,0269		0,50		Algorithm converged.	0,27	0,92
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	PAROTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC INFLAMMATORY DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERICORONITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIODONTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008		2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	7	1,5	517	28,4	4	0,8	1,89		Algorithm converged.	0,55	6,50	0,007		Algorithm converged.	-0,006	0,020		1,88		Algorithm converged.	0,55	6,37	0,3126		0,53		Algorithm converged.	0,16	1,81
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL NERVE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERTUSSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016	0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	40	4,9	824	45,2	36	4,4	1,13		Algorithm converged.	0,71	1,79	0,005		Algorithm converged.	-0,015	0,026	1,12		Algorithm converged.	0,72	1,75	0,6003		0,89		Algorithm converged.	0,57	1,38
		Asia Pacific	482	27,0	24	5,0	517	28,4	19	3,7	1,37		Algorithm converged.	0,74	2,54	0,013		Algorithm converged.	-0,012	0,038	1,35		Algorithm converged.	0,75	2,44	0,3121		0,74		Algorithm converged.	0,41	1,33
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	4	2,2	184	10,1	7	3,8	0,57		Algorithm converged.	0,16	1,96	-0,016		Algorithm converged.	-0,051	0,019	0,57		Algorithm converged.	0,17	1,93	0,3699		1,74		Algorithm converged.	0,52	5,84
	PHARYNGITIS BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PHARYNGITIS STREPTOCOCCAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PHARYNGOTONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PILONIDAL CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCYSTIS JIROVECII PNEUMONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	9	3,4	252	13,8	7	2,8	1,25		Algorithm converged.	0,46	3,40	0,007		Algorithm converged.	-0,023	0,037	1,24		Algorithm converged.	0,47	3,27	0,6686	-	0,81		Algorithm converged.	0,31	2,14
		Western Europe	814	45,7	12	1,5	824	45,2	12	1,5	1,01		Algorithm converged.	0,45	2,27	0,000		Algorithm converged.	-0,011	0,012	1,01		Algorithm converged.	0,46	2,24	0,9760		0,99		Algorithm converged.	0,45	2,19
		Asia Pacific	482	27,0	15	3,1	517	28,4	13	2,5	1,25		Algorithm converged.	0,59	2,64	0,006		Algorithm converged.	-0,015	0,027	1,24		Algorithm converged.	0,60	2,57	0,5682		0,81		Algorithm converged.	0,39	1,68
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	4	2,2	184	10,1	2	1,1	2,03		Algorithm converged.	0,37	11,24	0,011		Algorithm converged.	-0,015	0,037	2,01		Algorithm converged.	0,37	10,84	0,4164		0,50		Algorithm converged.	0,09	2,68
	PNEUMONIA ASPIRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA CHLAMYDIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMEMBRANOUS COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PSEUDOMONAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY TUBERCULOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULPITIS DENTAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PURULENT DISCHARGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PUSTULE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-		1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662			1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PYELONEPHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYODERMA STREPTOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	RADIATION SITE INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	RASH PUSTULAR	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007		0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79	
		Western Europe	814	45,7	15	1,8	824	45,2	5	0,6	3,08		Algorithm converged.	1,11	8,50	0,012		Algorithm converged.	0,002	0,023		3,04		Algorithm converged.	1,11	8,32	0,0307		0,33		Algorithm converged.	0,12	0,90	
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	17	2,1	824	45,2	8	1,0	2,18		Algorithm converged.	0,93	5,07	0,011		Algorithm converged.	-0,001	0,023	2,15		Algorithm converged.	0,93	4,96	0,0721		0,46		Algorithm converged.	0,20	1,07
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.073145902 3 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	RESPIRATORY TRACT INFECTION VIRAL	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	8	4,4	184	10,1	13	7,1	0,60		Algorithm converged.	0,24	1,49	-0,027		Algorithm converged.	-0,074	0,020	0,62		Algorithm converged.	0,26	1,46	0,2720		1,62		Algorithm converged.	0,69	3,81
	RHINITIS	USA/Canada	262	14,7	13	5,0	252	13,8	7	2,8	1,83		Algorithm converged.	0,72	4,66	0,022		Algorithm converged.	-0,011	0,055	1,79		Algorithm converged.	0,72	4,40	0,2077	-	0,56		Algorithm converged.	0,23	1,38
		Western Europe	814	45,7	72	8,8	824	45,2	67	8,1	1,10		Algorithm converged.	0,77	1,55	0,007		Algorithm converged.	-0,020	0,034	1,09		Algorithm converged.	0,79	1,50	0,6042		0,92		Algorithm converged.	0,67	1,26
		Asia Pacific	482	27,0	14	2,9	517	28,4	5	1,0	3,06		Algorithm converged.	1,09	8,57	0,019		Algorithm converged.	0,002	0,037	3,00		Algorithm converged.	1,09	8,28	0,0335		0,33		Algorithm converged.	0,12	0,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812879 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	4	2,2	184	10,1	2	1,1	2,03		Algorithm converged.	0,37	11,24	0,011		Algorithm converged.	-0,015	0,037	2,01		Algorithm converged.	0,37	10,84	0,4164		0,50		Algorithm converged.	0,09	2,68
	RHINOVIRUS INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEBACEOUS GLAND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEPSIS	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002		0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERRATIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	USA/Canada	262	14,7	25	9,5	252	13,8	29	11,5	0,81		Algorithm converged.	0,46	1,43	-0,020		Algorithm converged.	-0,073	0,033	0,83		Algorithm converged.	0,50	1,38	0,4682	-	1,21		Algorithm converged.	0,73	2,00
		Western Europe	814	45,7	12	1,5	824	45,2	16	1,9	0,76		Algorithm converged.	0,36	1,61	-0,005		Algorithm converged.	-0,017	0,008	0,76		Algorithm converged.	0,36	1,59	0,4669		1,32		Algorithm converged.	0,63	2,77
		Asia Pacific	482	27,0	7	1,5	517	28,4	4	0,8	1,89		Algorithm converged.	0,55	6,50	0,007		Algorithm converged.	-0,006	0,020	1,88		Algorithm converged.	0,55	6,37	0,3126		0,53		Algorithm converged.	0,16	1,81
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	SINUSITIS BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN CANDIDA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	USA/Canada	262	14,7	13	5,0	252	13,8	8	3,2	1,59		Algorithm converged.	0,65	3,91	0,018		Algorithm converged.	-0,016	0,052	1,56		Algorithm converged.	0,66	3,71	0,3108	-	0,64		Algorithm converged.	0,27	1,52
		Western Europe	814	45,7	15	1,8	824	45,2	12	1,5	1,27		Algorithm converged.	0,59	2,73	0,004		Algorithm converged.	-0,008	0,016	1,27		Algorithm converged.	0,60	2,69	0,5401		0,79		Algorithm converged.	0,37	1,68
		Asia Pacific	482	27,0	11	2,3	517	28,4	7	1,4	1,70		Algorithm converged.	0,65	4,43	0,009		Algorithm converged.	-0,007	0,026	1,69		Algorithm converged.	0,66	4,31	0,2761		0,59		Algorithm converged.	0,23	1,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SOFT TISSUE INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRONGYLOIDIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCUTANEOUS ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA CAPITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	TINEA CRURIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	TINEA INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77						
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011		1,61		Algorithm converged.	0,27	9,59	0,6015			0,62		Algorithm converged.	0,10	3,70						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA PEDIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	5	1,0	0,86		Algorithm converged.	0,23	3,21	-0,001		Algorithm converged.	-0,013	0,010	0,86		Algorithm converged.	0,23	3,18	0,8187		1,17		Algorithm converged.	0,31	4,31
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	10	1,2	0,40		Algorithm converged.	0,13	1,29	-0,007		Algorithm converged.	-0,016	0,002	0,40		Algorithm converged.	0,13	1,29	0,1251		2,47		Algorithm converged.	0,78	7,84
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44	
	TOOTH ABSCESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010		1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48	
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOOTH INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	9	1,1	824	45,2	11	1,3	0,83		Algorithm converged.	0,34	2,00	-0,002		Algorithm converged.	-0,013	0,008	0,83		Algorithm converged.	0,35	1,99	0,6731		1,21		Algorithm converged.	0,50	2,90
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRACHEITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	9	1,1	0,33		Algorithm converged.	0,09	1,24	-0,007		Algorithm converged.	-0,015	0,001	0,34		Algorithm converged.	0,09	1,24	0,1022		2,96		Algorithm converged.	0,81	10,91
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	5	2,7	184	10,1	1	0,5	5,14		Algorithm converged.	0,59	44,44	0,022		Algorithm converged.	-0,004	0,048	5,03		Algorithm converged.	0,59	42,61	0,1386		0,20		Algorithm converged.	0,02	1,69
	TRACHEOBRONCHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	5	2,7	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRICHOPHYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	39	14,9	252	13,8	40	15,9	0,93		Algorithm converged.	0,57	1,50	-0,010		Algorithm converged.	-0,072	0,053	0,94		Algorithm converged.	0,63	1,41	0,7564	-	1,07		Algorithm converged.	0,71	1,60
		Western Europe	814	45,7	28	3,4	824	45,2	18	2,2	1,60		Algorithm converged.	0,88	2,91	0,013		Algorithm converged.	-0,003	0,029	1,57		Algorithm converged.	0,88	2,82	0,1277		0,64		Algorithm converged.	0,35	1,14
		Asia Pacific	482	27,0	60	12,4	517	28,4	65	12,6	0,99		Algorithm converged.	0,68	1,44	-0,001		Algorithm converged.	-0,042	0,040	0,99		Algorithm converged.	0,71	1,37	0,9526		1,01		Algorithm converged.	0,73	1,40
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	12	6,6	184	10,1	13	7,1	0,92		Algorithm converged.	0,41	2,08	-0,005		Algorithm converged.	-0,057	0,046	0,93		Algorithm converged.	0,44	1,98	0,8469		1,08		Algorithm converged.	0,51	2,30
	URETHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION	USA/Canada	262	14,7	43	16,4	252	13,8	31	12,3	1,40		Algorithm converged.	0,85	2,30	0,041		Algorithm converged.	-0,019	0,102	1,33		Algorithm converged.	0,87	2,05	0,1870	0,2230	0,75		Algorithm converged.	0,49	1,15
		Western Europe	814	45,7	58	7,1	824	45,2	69	8,4	0,84		Algorithm converged.	0,58	1,21	-0,012		Algorithm converged.	-0,038	0,013	0,85		Algorithm converged.	0,61	1,19	0,3455		1,18		Algorithm converged.	0,84	1,64
		Asia Pacific	482	27,0	24	5,0	517	28,4	14	2,7	1,88		Algorithm converged.	0,96	3,68	0,023		Algorithm converged.	-0,001	0,047	1,84		Algorithm converged.	0,96	3,51	0,0652		0,54		Algorithm converged.	0,28	1,04
		Latin America	42	2,4	6	14,3	45	2,5	6	13,3	1,08		Algorithm converged.	0,32	3,67	0,010		Algorithm converged.	-0,136	0,155	1,07		Algorithm converged.	0,37	3,06	0,8976		0,93		Algorithm converged.	0,33	2,67
		Other	183	10,3	8	4,4	184	10,1	6	3,3	1,36		Algorithm converged.	0,46	3,99	0,011		Algorithm converged.	-0,028	0,050	1,34		Algorithm converged.	0,47	3,79	0,5801		0,75		Algorithm converged.	0,26	2,11
	URINARY TRACT INFECTION ENTEROCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION STAPHYLOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	UROSEPSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL ABSCESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL INFECTION	USA/Canada	262	14,7	5	1,9	252	13,8	5	2,0	0,96		Algorithm converged.	0,27	3,36	-0,001		Algorithm converged.	-0,025	0,023	0,96		Algorithm converged.	0,28	3,28	0,9505	-	1,04		Algorithm converged.	0,30	3,55
		Western Europe	814	45,7	14	1,7	824	45,2	10	1,2	1,42		Algorithm converged.	0,63	3,23	0,005		Algorithm converged.	-0,007	0,017	1,42		Algorithm converged.	0,63	3,17	0,3963		0,71		Algorithm converged.	0,32	1,58
		Asia Pacific	482	27,0	2	0,4	517	28,4	10	1,9	0,21		Algorithm converged.	0,05	0,97	-0,015		Algorithm converged.	-0,028	-0,002	0,21		Algorithm converged.	0,05	0,97	0,0462		4,66		Algorithm converged.	1,03	21,17
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	VAGINITIS GARDNERELLA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VARICELLA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VARICELLA ZOSTER VIRUS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR DEVICE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	5	0,6	824	45,2	6	0,7	0,84		Algorithm converged.	0,26	2,77	-0,001		Algorithm converged.	-0,009	0,007	0,84		Algorithm converged.	0,26	2,75	0,7780		1,19		Algorithm converged.	0,36	3,87
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VESTIBULAR NEURONITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VESTIBULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011		1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	6	3,3	184	10,1	7	3,8	0,86		Algorithm converged.	0,28	2,60	-0,005		Algorithm converged.	-0,043	0,033		0,86		Algorithm converged.	0,30	2,52	0,7855		1,16		Algorithm converged.	0,40	3,39
	VIRAL PHARYNGITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL RHINITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL SINUSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL TRACHEITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	15	1,8	824	45,2	5	0,6	3,08		Algorithm converged.	1,11	8,50	0,012		Algorithm converged.	0,002	0,023	3,04		Algorithm converged.	1,11	8,32	0,0307		0,33		Algorithm converged.	0,12	0,90
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL MYCOTIC INFECTION	USA/Canada	262	14,7	10	3,8	252	13,8	5	2,0	1,96		Algorithm converged.	0,66	5,82	0,018		Algorithm converged.	-0,011	0,047	1,92		Algorithm converged.	0,67	5,55	0,2262	-	0,52		Algorithm converged.	0,18	1,50
		Western Europe	814	45,7	11	1,4	824	45,2	9	1,1	1,24		Algorithm converged.	0,51	3,01	0,003		Algorithm converged.	-0,008	0,013	1,24		Algorithm converged.	0,52	2,97	0,6337		0,81		Algorithm converged.	0,34	1,94
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	1	0,5	3,05		Algorithm converged.	0,31	29,60	0,011		Algorithm converged.	-0,010	0,032	3,02		Algorithm converged.	0,32	28,73	0,3370		0,33		Algorithm converged.	0,03	3,16
	VULVOVAGINITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	WOUND ABSCESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	5	0,6	824	45,2	8	1,0	0,63		Algorithm converged.	0,21	1,94	-0,004		Algorithm converged.	-0,012	0,005	0,63		Algorithm converged.	0,21	1,93	0,4202		1,58		Algorithm converged.	0,52	4,81
		Asia Pacific	482	27,0	5	1,0	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	WOUND INFECTION STAPHYLOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	106	40,5	252	13,8	96	38,1	1,10		Algorithm converged.	0,77	1,57	0,024		Algorithm converged.	-0,061	0,108		1,06		Algorithm converged.	0,86	1,32	0,5838	0,9703	0,94		Algorithm converged.	0,76	1,17
		Western Europe	814	45,7	191	23,5	824	45,2	185	22,5	1,06		Algorithm converged.	0,84	1,33	0,010		Algorithm converged.	-0,031	0,051		1,05		Algorithm converged.	0,88	1,25	0,6260		0,96		Algorithm converged.	0,80	1,14
		Asia Pacific	482	27,0	134	27,8	517	28,4	125	24,2	1,21		Algorithm converged.	0,91	1,60	0,036		Algorithm converged.	-0,018	0,091		1,15		Algorithm converged.	0,93	1,42	0,1920		0,87		Algorithm converged.	0,71	1,07
		Latin America	42	2,4	9	21,4	45	2,5	9	20,0	1,09		Algorithm converged.	0,39	3,08	0,014		Algorithm converged.	-0,156	0,185		1,07		Algorithm converged.	0,47	2,44	0,8694		0,93		Algorithm converged.	0,41	2,12
		Other	183	10,3	34	18,6	184	10,1	33	17,9	1,04		Algorithm converged.	0,61	1,77	0,006		Algorithm converged.	-0,073	0,085		1,04		Algorithm converged.	0,67	1,60	0,8731		0,97		Algorithm converged.	0,63	1,49
	ACCIDENTAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANIMAL BITE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANIMAL SCRATCH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ANKLE FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ARTHROPOD BITE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53	
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006		0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58	
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012		3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARTHROPOD STING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AVULSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY WEB SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BITE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST PROCEDURAL COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURN ORAL CAVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURNS SECOND DEGREE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL BURN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL BURNS OF EYE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL PHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHILLBLAINS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CONCUSSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CONTUSION	USA/Canada	262	14,7	13	5,0	252	13,8	8	3,2	1,59		Algorithm converged.	0,65	3,91	0,018		Algorithm converged.	-0,016	0,052	1,56		Algorithm converged.	0,66	3,71	0,3108	-	0,64		Algorithm converged.	0,27	1,52	
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84	
		Asia Pacific	482	27,0	5	1,0	517	28,4	5	1,0	1,07		Algorithm converged.	0,31	3,73	0,001		Algorithm converged.	-0,012	0,013	1,07		Algorithm converged.	0,31	3,68	0,9113		0,93		Algorithm converged.	0,27	3,20	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	DENTAL RESTORATION FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPICONDYLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ESCHAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE CONTUSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FACIAL BONES FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FALL	USA/Canada	262	14,7	4	1,5	252	13,8	9	3,6	0,42		Algorithm converged.	0,13	1,38	-0,020		Algorithm converged.	-0,048	0,007	0,43		Algorithm converged.	0,13	1,37	0,1528	-	2,34		Algorithm converged.	0,73	7,50
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009	1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEMORAL NECK FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	FOOT FRACTURE	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31	
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	FOREIGN BODY IN THROAT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FRACTURED SACRUM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ILIUM FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE COMPLICATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE PAIN	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021	0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	6	1,2	517	28,4	5	1,0	1,29		Algorithm converged.	0,39	4,26	0,003		Algorithm converged.	-0,010	0,016	1,29		Algorithm converged.	0,40	4,19	0,6751		0,78		Algorithm converged.	0,24	2,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED REACTION	USA/Canada	262	14,7	10	3,8	252	13,8	12	4,8	0,79		Algorithm converged.	0,34	1,87	-0,009		Algorithm converged.	-0,045	0,026	0,80		Algorithm converged.	0,35	1,82	0,5975	-	1,25		Algorithm converged.	0,55	2,84
		Western Europe	814	45,7	18	2,2	824	45,2	19	2,3	0,96		Algorithm converged.	0,50	1,84	-0,001		Algorithm converged.	-0,015	0,013	0,96		Algorithm converged.	0,51	1,81	0,8976		1,04		Algorithm converged.	0,55	1,97
		Asia Pacific	482	27,0	38	7,9	517	28,4	30	5,8	1,39		Algorithm converged.	0,85	2,28	0,021		Algorithm converged.	-0,011	0,052	1,36		Algorithm converged.	0,86	2,16	0,1938		0,74		Algorithm converged.	0,46	1,17
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT INJURY	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013		0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	LIGAMENT SPRAIN	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002		0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	4	0,8	0,27		Algorithm converged.	0,03	2,39	-0,006		Algorithm converged.	-0,014	0,003		0,27		Algorithm converged.	0,03	2,39	0,2383		3,73		Algorithm converged.	0,42	33,25
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIMB INJURY	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER LIMB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE RUPTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCLE STRAIN	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	NAIL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PELVIC FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PNEUMOTHORAX TRAUMATIC	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	POISONING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	POST PROCEDURAL HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	POST PROCEDURAL SWELLING	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	POSTMASTECTOMY LYMPHOEDEMA SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk								
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL DIZZINESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021	0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6	0,61		Algorithm converged.	0,14	2,54	-0,002		Algorithm converged.	-0,009	0,004	0,61		Algorithm converged.	0,15	2,53	0,4938		1,65		Algorithm converged.	0,39	6,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005	0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY RADIATION INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005	0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION ASSOCIATED PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2	4,32		Algorithm converged.	0,48	38,77	0,006		Algorithm converged.	-0,003	0,015	4,29		Algorithm converged.	0,48	38,25	0,1920		0,23		Algorithm converged.	0,03	2,08
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	RADIATION INJURY	USA/Canada	262	14,7	10	3,8	252	13,8	6	2,4	1,63		Algorithm converged.	0,58	4,54	0,014		Algorithm converged.	-0,016	0,044		1,60		Algorithm converged.	0,59	4,35	0,3537	-		0,62		Algorithm converged.	0,23	1,69
		Western Europe	814	45,7	26	3,2	824	45,2	28	3,4	0,94		Algorithm converged.	0,55	1,61	-0,002		Algorithm converged.	-0,019	0,015		0,94		Algorithm converged.	0,56	1,59	0,8172			1,06		Algorithm converged.	0,63	1,80
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011		1,61		Algorithm converged.	0,27	9,59	0,6015			0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606			0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	3	1,6	184	10,1	4	2,2	0,75		Algorithm converged.	0,17	3,40	-0,005		Algorithm converged.	-0,033	0,023		0,75		Algorithm converged.	0,17	3,32	0,7091			1,33		Algorithm converged.	0,30	5,84
	RADIATION NECROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	RADIATION NEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION OESOPHAGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION PNEUMONITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	9	1,9	517	28,4	4	0,8	2,44		Algorithm converged.	0,75	7,98	0,011		Algorithm converged.	-0,003	0,025	2,41		Algorithm converged.	0,75	7,79	0,1404		0,41		Algorithm converged.	0,13	1,34
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION SKIN INJURY	USA/Canada	262	14,7	61	23,3	252	13,8	43	17,1	1,48		Algorithm converged.	0,95	2,28	0,062		Algorithm converged.	-0,007	0,131	1,36		Algorithm converged.	0,96	1,94	0,0817	-	0,73		Algorithm converged.	0,52	1,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	88	10,8	824	45,2	80	9,7	1,13		Algorithm converged.	0,82	1,55	0,011		Algorithm converged.	-0,018	0,040		1,11		Algorithm converged.	0,84	1,48	0,4626		0,90		Algorithm converged.	0,67	1,20
		Asia Pacific	482	27,0	68	14,1	517	28,4	59	11,4	1,28		Algorithm converged.	0,88	1,85	0,027		Algorithm converged.	-0,014	0,068		1,24		Algorithm converged.	0,89	1,71	0,2022		0,81		Algorithm converged.	0,58	1,12
		Latin America	42	2,4	4	9,5	45	2,5	3	6,7	1,47		Algorithm converged.	0,31	7,01	0,029		Algorithm converged.	-0,086	0,143		1,43		Algorithm converged.	0,34	6,01	0,6265		0,70		Algorithm converged.	0,17	2,94
		Other	183	10,3	23	12,6	184	10,1	19	10,3	1,25		Algorithm converged.	0,65	2,38	0,022		Algorithm converged.	-0,043	0,088		1,22		Algorithm converged.	0,69	2,16	0,5008		0,82		Algorithm converged.	0,46	1,46
	RADIUS FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RECALL PHENOMENON	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,004		Algorithm converged.	-0,010	0,003		0,40		Algorithm converged.	0,08	2,08	0,2790		2,47		Algorithm converged.	0,48	12,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RIB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021	0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN ABRASION	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LACERATION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRESS FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDON INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TENDON RUPTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	THERMAL BURN	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005		0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95	
		Western Europe	814	45,7	8	1,0	824	45,2	3	0,4	2,72		Algorithm converged.	0,72	10,28	0,006		Algorithm converged.	-0,002	0,014		2,70		Algorithm converged.	0,72	10,14	0,1414		0,37		Algorithm converged.	0,10	1,39	
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	THORACIC VERTEBRAL FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TIBIA FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSFUSION REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRAUMATIC HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULNA FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	UPPER LIMB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIITH NERVE INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WOUND	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006		0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	7	1,5	517	28,4	2	0,4	3,79		Algorithm converged.	0,78	18,36	0,011		Algorithm converged.	-0,001	0,023	3,75		Algorithm converged.	0,78	17,98	0,0979		0,27		Algorithm converged.	0,06	1,28
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	WOUND HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND SECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	USA/Canada	262	14,7	108	41,2	252	13,8	119	47,2	0,78		Algorithm converged.	0,55	1,11	-0,060		Algorithm converged.	-0,146	0,026	0,87		Algorithm converged.	0,72	1,06	0,1715	0,2804	1,15		Algorithm converged.	0,94	1,39
		Western Europe	814	45,7	290	35,6	824	45,2	319	38,7	0,88		Algorithm converged.	0,72	1,07	-0,031		Algorithm converged.	-0,078	0,016	0,92		Algorithm converged.	0,81	1,04	0,1966		1,09		Algorithm converged.	0,96	1,23
		Asia Pacific	482	27,0	305	63,3	517	28,4	308	59,6	1,17		Algorithm converged.	0,91	1,51	0,037		Algorithm converged.	-0,023	0,097	1,06		Algorithm converged.	0,96	1,17	0,2293		0,94		Algorithm converged.	0,85	1,04
		Latin America	42	2,4	10	23,8	45	2,5	12	26,7	0,86		Algorithm converged.	0,33	2,27	-0,029		Algorithm converged.	-0,211	0,154	0,89		Algorithm converged.	0,43	1,85	0,7597		1,12		Algorithm converged.	0,54	2,32
		Other	183	10,3	42	23,0	184	10,1	46	25,0	0,89		Algorithm converged.	0,55	1,44	-0,020		Algorithm converged.	-0,108	0,067	0,92		Algorithm converged.	0,64	1,32	0,6459		1,09		Algorithm converged.	0,76	1,57
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	17	6,5	252	13,8	27	10,7	0,58		Algorithm converged.	0,31	1,09	-0,042		Algorithm converged.	-0,091	0,006	0,61		Algorithm converged.	0,34	1,08	0,0910	-	1,65		Algorithm converged.	0,92	2,95
		Western Europe	814	45,7	51	6,3	824	45,2	46	5,6	1,13		Algorithm converged.	0,75	1,70	0,007		Algorithm converged.	-0,016	0,030	1,12		Algorithm converged.	0,76	1,65	0,5585		0,89		Algorithm converged.	0,61	1,31
		Asia Pacific	482	27,0	95	19,7	517	28,4	103	19,9	0,99		Algorithm converged.	0,72	1,35	-0,002		Algorithm converged.	-0,052	0,047	0,99		Algorithm converged.	0,77	1,27	0,9327		1,01		Algorithm converged.	0,79	1,30
		Latin America	42	2,4	3	7,1	45	2,5	5	11,1	0,62		Algorithm converged.	0,14	2,75	-0,040		Algorithm converged.	-0,160	0,081	0,64		Algorithm converged.	0,16	2,53	0,5268		1,56		Algorithm converged.	0,40	6,11
		Other	183	10,3	10	5,5	184	10,1	15	8,2	0,65		Algorithm converged.	0,28	1,49	-0,027		Algorithm converged.	-0,078	0,025	0,67		Algorithm converged.	0,31	1,45	0,3108		1,49		Algorithm converged.	0,69	3,23

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASPARTATE AMINOTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	11	4,2	252	13,8	25	9,9	0,40		Algorithm converged.	0,19	0,83	-0,057		Algorithm converged.	-0,101	-0,013	0,42		Algorithm converged.	0,21	0,84	0,0143	0,0280	2,36		Algorithm converged.	1,19	4,70
		Western Europe	814	45,7	28	3,4	824	45,2	33	4,0	0,85		Algorithm converged.	0,51	1,43	-0,006		Algorithm converged.	-0,024	0,013	0,86		Algorithm converged.	0,52	1,41	0,5464		1,16		Algorithm converged.	0,71	1,91
		Asia Pacific	482	27,0	65	13,5	517	28,4	53	10,3	1,36		Algorithm converged.	0,93	2,01	0,032		Algorithm converged.	-0,008	0,073	1,32		Algorithm converged.	0,94	1,85	0,1149		0,76		Algorithm converged.	0,54	1,07
		Latin America	42	2,4	3	7,1	45	2,5	7	15,6	0,42		Algorithm converged.	0,10	1,74	-0,084		Algorithm converged.	-0,216	0,047	0,46		Algorithm converged.	0,13	1,66	0,2354		2,18		Algorithm converged.	0,60	7,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	12	6,6	184	10,1	12	6,5	1,01		Algorithm converged.	0,44	2,30	0,000		Algorithm converged.	-0,050	0,051	1,01		Algorithm converged.	0,46	2,18	0,9890		0,99		Algorithm converged.	0,46	2,16
	BILIRUBIN CONJUGATED INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD ALKALINE PHOSPHATASE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD ALKALINE PHOSPHATASE INCREASED	USA/Canada	262	14,7	5	1,9	252	13,8	11	4,4	0,43		Algorithm converged.	0,15	1,24	-0,025		Algorithm converged.	-0,055	0,006	0,44		Algorithm converged.	0,15	1,24	0,1200	-	2,29		Algorithm converged.	0,81	6,49
		Western Europe	814	45,7	11	1,4	824	45,2	8	1,0	1,40		Algorithm converged.	0,56	3,49	0,004		Algorithm converged.	-0,007	0,014	1,39		Algorithm converged.	0,56	3,44	0,4742		0,72		Algorithm converged.	0,29	1,78
		Asia Pacific	482	27,0	10	2,1	517	28,4	11	2,1	0,97		Algorithm converged.	0,41	2,32	-0,001		Algorithm converged.	-0,018	0,017	0,98		Algorithm converged.	0,42	2,28	0,9535		1,03		Algorithm converged.	0,44	2,39
		Latin America	42	2,4	3	7,1	45	2,5	4	8,9	0,79		Algorithm converged.	0,17	3,75	-0,017		Algorithm converged.	-0,131	0,096	0,80		Algorithm converged.	0,19	3,38	0,7654		1,24		Algorithm converged.	0,30	5,23
		Other	183	10,3	2	1,1	184	10,1	6	3,3	0,33		Algorithm converged.	0,07	1,65	-0,022		Algorithm converged.	-0,051	0,008	0,34		Algorithm converged.	0,07	1,64	0,1770		2,98		Algorithm converged.	0,61	14,59
	BLOOD BILIRUBIN DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014	1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BLOOD BILIRUBIN UNCONJUGATED INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOOD CALCIUM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOOD CALCIUM DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHLORIDE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	7	0,9	824	45,2	7	0,8	1,01		Algorithm converged.	0,35	2,90	0,000		Algorithm converged.	-0,009	0,009	1,01		Algorithm converged.	0,36	2,87	0,9817		0,99		Algorithm converged.	0,35	2,80
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATINE PHOSPHOKINASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	6	2,3	252	13,8	3	1,2	1,95		Algorithm converged.	0,48	7,86	0,011		Algorithm converged.	-0,012	0,034	1,92		Algorithm converged.	0,49	7,61	0,3511	-	0,52		Algorithm converged.	0,13	2,06	
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006	0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58	
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOOD GLUCOSE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD GLUCOSE FLUCTUATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BLOOD GLUCOSE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-		2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD LACTATE DEHYDROGENASE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	12	1,5	824	45,2	5	0,6	2,45		Algorithm converged.	0,86	6,99	0,009		Algorithm converged.	-0,001	0,019	2,43		Algorithm converged.	0,86	6,87	0,0940		0,41		Algorithm converged.	0,15	1,16
		Asia Pacific	482	27,0	8	1,7	517	28,4	9	1,7	0,95		Algorithm converged.	0,36	2,49	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,37	2,45	0,9212		1,05		Algorithm converged.	0,41	2,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.532081293 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	BLOOD MAGNESIUM DECREASED	USA/Canada	262	14,7	2	0,8	252	13,8	6	2,4	0,32		Algorithm converged.	0,06	1,58	-0,016		Algorithm converged.	-0,038	0,005	0,32		Algorithm converged.	0,07	1,57	0,1611	-	3,12		Algorithm converged.	0,64	15,31
		Western Europe	814	45,7	7	0,9	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD MAGNESIUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD PHOSPHORUS DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PHOSPHORUS INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	4	0,8	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	0,031	*	WARNING: The relative Hessian convergence criterion of 18.885863169 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,121	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD POTASSIUM DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD POTASSIUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DIASTOLIC DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DIASTOLIC INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	BLOOD SODIUM DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD SODIUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD UREA DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BLOOD UREA INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779			1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013		1,43		Algorithm converged.	0,32	6,36	0,6383			0,70		Algorithm converged.	0,16	3,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD URIC ACID INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD URINE PRESENT	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	BODY TEMPERATURE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	BREATH SOUNDS ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	C-REACTIVE PROTEIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,005		Algorithm converged.	-0,012	0,002	0,34		Algorithm converged.	0,07	1,67	0,1825		2,96		Algorithm converged.	0,60	14,64
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARBOHYDRATE ANTIGEN 125 INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARBOHYDRATE ANTIGEN 15-3 INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC MURMUR	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM TEST POSITIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CREATININE RENAL CLEARANCE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DELTARETROVIRUS TEST POSITIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ECHOCARDIOGRAM ABNORMAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	USA/Canada	262	14,7	20	7,6	252	13,8	23	9,1	0,82		Algorithm converged.	0,44	1,54	-0,015		Algorithm converged.	-0,063	0,033		0,84		Algorithm converged.	0,47	1,48	0,5416	-	1,20		Algorithm converged.	0,67	2,12
		Western Europe	814	45,7	46	5,7	824	45,2	72	8,7	0,63		Algorithm converged.	0,43	0,92	-0,031		Algorithm converged.	-0,056	-0,006		0,65		Algorithm converged.	0,45	0,92	0,0167		1,55		Algorithm converged.	1,08	2,21
		Asia Pacific	482	27,0	15	3,1	517	28,4	10	1,9	1,63		Algorithm converged.	0,72	3,66	0,012		Algorithm converged.	-0,008	0,031		1,61		Algorithm converged.	0,73	3,55	0,2383		0,62		Algorithm converged.	0,28	1,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	3	7,1	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	3	1,6	184	10,1	7	3,8	0,42		Algorithm converged.	0,11	1,66	-0,022		Algorithm converged.	-0,055	0,012	0,43		Algorithm converged.	0,11	1,64	0,2171		2,32		Algorithm converged.	0,61	8,84
	ELECTROCARDIOGRAM ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ELECTROCARDIOGRAM QT PROLONGED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ELECTROCARDIOGRAM ST-T CHANGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM T WAVE ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROCARDIOGRAM T WAVE INVERSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHIL COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHIL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FORCED EXPIRATORY VOLUME DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	6	0,7	824	45,2	15	1,8	0,40		Algorithm converged.	0,15	1,04	-0,011		Algorithm converged.	-0,022	0,000	0,40		Algorithm converged.	0,16	1,04	0,0599		2,47		Algorithm converged.	0,96	6,33
		Asia Pacific	482	27,0	10	2,1	517	28,4	19	3,7	0,56		Algorithm converged.	0,26	1,21	-0,016		Algorithm converged.	-0,037	0,005	0,56		Algorithm converged.	0,27	1,20	0,1381		1,77		Algorithm converged.	0,83	3,77
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	GLOMERULAR FILTRATION RATE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLYCOSYLATED HAEMOGLOBIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOCRIT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOGLOBIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	9	1,1	824	45,2	11	1,3	0,83		Algorithm converged.	0,34	2,00	-0,002		Algorithm converged.	-0,013	0,008	0,83		Algorithm converged.	0,35	1,99	0,6731		1,21		Algorithm converged.	0,50	2,90
		Asia Pacific	482	27,0	43	8,9	517	28,4	47	9,1	0,98		Algorithm converged.	0,63	1,51	-0,002		Algorithm converged.	-0,037	0,034	0,98		Algorithm converged.	0,66	1,46	0,9254		1,02		Algorithm converged.	0,69	1,51
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOGLOBIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAPTOGLOBIN DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEART RATE INCREASED	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HELICOBACTER TEST POSITIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC ENZYME ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC ENZYME INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMAN CHORIONIC GONADOTROPIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.997887329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	USA/Canada	262	14,7	6	2,3	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	8	1,0	0,88		Algorithm converged.	0,32	2,45	-0,001		Algorithm converged.	-0,010	0,008		0,89		Algorithm converged.	0,32	2,43	0,8138		1,13		Algorithm converged.	0,41	3,10
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	LYMPHOCYTE COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MEGAKARYOCYTES ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAMYELOCYTE COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONONUCLEAR CELL COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6	0,61		Algorithm converged.	0,14	2,54	-0,002		Algorithm converged.	-0,009	0,004	0,61		Algorithm converged.	0,15	2,53	0,4938		1,65		Algorithm converged.	0,39	6,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	16	6,1	252	13,8	21	8,3	0,72		Algorithm converged.	0,36	1,40	-0,022		Algorithm converged.	-0,067	0,023		0,73		Algorithm converged.	0,39	1,37	0,3312	-	1,36		Algorithm converged.	0,73	2,55
		Western Europe	814	45,7	74	9,1	824	45,2	89	10,8	0,83		Algorithm converged.	0,60	1,14	-0,017		Algorithm converged.	-0,046	0,012		0,84		Algorithm converged.	0,63	1,13	0,2485		1,19		Algorithm converged.	0,89	1,59
		Asia Pacific	482	27,0	166	34,4	517	28,4	148	28,6	1,31		Algorithm converged.	1,00	1,71	0,058		Algorithm converged.	0,001	0,116		1,20		Algorithm converged.	1,00	1,45	0,0484		0,83		Algorithm converged.	0,69	1,00
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	6	3,3	184	10,1	6	3,3	1,01		Algorithm converged.	0,32	3,18	0,000		Algorithm converged.	-0,036	0,037		1,01		Algorithm converged.	0,33	3,06	0,9923		0,99		Algorithm converged.	0,33	3,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHYSICAL EXAMINATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHYSICAL EXAMINATION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	14	5,3	252	13,8	10	4,0	1,37		Algorithm converged.	0,60	3,13	0,014		Algorithm converged.	-0,023	0,050	1,35		Algorithm converged.	0,61	2,98	0,4620	-	0,74		Algorithm converged.	0,34	1,64
		Western Europe	814	45,7	19	2,3	824	45,2	22	2,7	0,87		Algorithm converged.	0,47	1,62	-0,003		Algorithm converged.	-0,018	0,012	0,87		Algorithm converged.	0,48	1,60	0,6639		1,14		Algorithm converged.	0,62	2,10
		Asia Pacific	482	27,0	29	6,0	517	28,4	31	6,0	1,00		Algorithm converged.	0,60	1,69	0,000		Algorithm converged.	-0,029	0,030	1,00		Algorithm converged.	0,61	1,64	0,9891		1,00		Algorithm converged.	0,61	1,63
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLATELET COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014	1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PROTEIN TOTAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PROTEIN TOTAL DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-					NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PROTEIN URINE PRESENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-					NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RED BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-					NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	16	3,3	517	28,4	11	2,1	1,58		Algorithm converged.	0,73	3,44	0,012		Algorithm converged.	-0,008	0,032	1,56		Algorithm converged.	0,73	3,33	0,2498		0,64		Algorithm converged.	0,30	1,37
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERUM FERRITIN DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMEAR CERVIX ABNORMAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID FUNCTION TEST ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID FUNCTION TEST NORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TRANSAMINASES DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TRANSAMINASES INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53	
		Western Europe	814	45,7	8	1,0	824	45,2	6	0,7	1,35		Algorithm converged.	0,47	3,92	0,003		Algorithm converged.	-0,006	0,011		1,35		Algorithm converged.	0,47	3,87	0,5771		0,74		Algorithm converged.	0,26	2,13	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	6	1,2	517	28,4	10	1,9	0,64		Algorithm converged.	0,23	1,77	-0,007		Algorithm converged.	-0,022	0,009	0,64		Algorithm converged.	0,24	1,76	0,3898		1,55		Algorithm converged.	0,57	4,24
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	TRANSFERRIN SATURATION DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN T INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINE ANALYSIS ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	URINE OUTPUT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITAMIN B12 DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN D DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	USA/Canada	262	14,7	35	13,4	252	13,8	18	7,1	2,00		Algorithm converged.	1,10	3,64	0,062		Algorithm converged.	0,010	0,114	1,87		Algorithm converged.	1,09	3,21	0,0235	-	0,53		Algorithm converged.	0,31	0,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	58	7,1	824	45,2	23	2,8	2,67		Algorithm converged.	1,63	4,37	0,043		Algorithm converged.	0,022	0,064	2,55		Algorithm converged.	1,59	4,10	0,0001		0,39		Algorithm converged.	0,24	0,63
		Asia Pacific	482	27,0	39	8,1	517	28,4	16	3,1	2,76		Algorithm converged.	1,52	5,00	0,050		Algorithm converged.	0,021	0,079	2,61		Algorithm converged.	1,48	4,62	0,0009		0,38		Algorithm converged.	0,22	0,68
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	6	3,3	184	10,1	7	3,8	0,86		Algorithm converged.	0,28	2,60	-0,005		Algorithm converged.	-0,043	0,033	0,86		Algorithm converged.	0,30	2,52	0,7855		1,16		Algorithm converged.	0,40	3,39
	WEIGHT INCREASED	USA/Canada	262	14,7	8	3,1	252	13,8	17	6,7	0,44		Algorithm converged.	0,18	1,03	-0,037		Algorithm converged.	-0,074	0,000	0,45		Algorithm converged.	0,20	1,03	0,0589	-	2,21		Algorithm converged.	0,97	5,03
		Western Europe	814	45,7	19	2,3	824	45,2	57	6,9	0,32		Algorithm converged.	0,19	0,55	-0,046		Algorithm converged.	-0,066	-0,026	0,34		Algorithm converged.	0,20	0,56	<.0001		2,96		Algorithm converged.	1,78	4,94
		Asia Pacific	482	27,0	16	3,3	517	28,4	26	5,0	0,65		Algorithm converged.	0,34	1,22	-0,017		Algorithm converged.	-0,042	0,008	0,66		Algorithm converged.	0,36	1,22	0,1822		1,51		Algorithm converged.	0,82	2,79
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	4	2,2	0,75		Algorithm converged.	0,17	3,40	-0,005		Algorithm converged.	-0,033	0,023	0,75		Algorithm converged.	0,17	3,32	0,7091		1,33		Algorithm converged.	0,30	5,84
	WHITE BLOOD CELL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	15	5,7	252	13,8	20	7,9	0,70		Algorithm converged.	0,35	1,41	-0,022		Algorithm converged.	-0,066	0,022	0,72		Algorithm converged.	0,38	1,38	0,3223	-	1,39		Algorithm converged.	0,73	2,65
		Western Europe	814	45,7	46	5,7	824	45,2	49	5,9	0,95		Algorithm converged.	0,63	1,43	-0,003		Algorithm converged.	-0,026	0,020	0,95		Algorithm converged.	0,64	1,40	0,7981		1,05		Algorithm converged.	0,71	1,56

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	136	28,2	517	28,4	98	19,0	1,68		Algorithm converged.	1,25	2,26	0,093		Algorithm converged.	0,040	0,145		1,49		Algorithm converged.	1,18	1,87	0,0006		0,67		Algorithm converged.	0,53	0,84
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812828 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	4	2,2	184	10,1	2	1,1	2,03		Algorithm converged.	0,37	11,24	0,011		Algorithm converged.	-0,015	0,037		2,01		Algorithm converged.	0,37	10,84	0,4164		0,50		Algorithm converged.	0,09	2,68
	WHITE BLOOD CELL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	151	57,6	252	13,8	135	53,6	1,18		Algorithm converged.	0,83	1,67	0,041		Algorithm converged.	-0,045	0,126	1,08		Algorithm converged.	0,92	1,26	0,3550	0,0202	0,93		Algorithm converged.	0,80	1,09
		Western Europe	814	45,7	225	27,6	824	45,2	170	20,6	1,47		Algorithm converged.	1,17	1,85	0,070		Algorithm converged.	0,029	0,111	1,34		Algorithm converged.	1,13	1,59	0,0010		0,75		Algorithm converged.	0,63	0,89
		Asia Pacific	482	27,0	197	40,9	517	28,4	216	41,8	0,96		Algorithm converged.	0,75	1,24	-0,009		Algorithm converged.	-0,070	0,052	0,98		Algorithm converged.	0,84	1,13	0,7709		1,02		Algorithm converged.	0,88	1,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	16	38,1	45	2,5	9	20,0	2,46		Algorithm converged.	0,94	6,43	0,181		Algorithm converged.	-0,007	0,369	1,90		Algorithm converged.	0,95	3,84	0,0712		0,53		Algorithm converged.	0,26	1,06
		Other	183	10,3	44	24,0	184	10,1	30	16,3	1,62		Algorithm converged.	0,97	2,73	0,077		Algorithm converged.	-0,004	0,159	1,47		Algorithm converged.	0,97	2,24	0,0676		0,68		Algorithm converged.	0,45	1,03
	ACIDOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPETITE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CACHEXIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELL DEATH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED APPETITE	USA/Canada	262	14,7	78	29,8	252	13,8	71	28,2	1,08		Algorithm converged.	0,74	1,58	0,016		Algorithm converged.	-0,062	0,094		1,06		Algorithm converged.	0,81	1,39	0,6902	-	0,95		Algorithm converged.	0,72	1,24
		Western Europe	814	45,7	154	18,9	824	45,2	114	13,8	1,45		Algorithm converged.	1,12	1,89	0,051		Algorithm converged.	0,015	0,087		1,37		Algorithm converged.	1,10	1,71	0,0057		0,73		Algorithm converged.	0,59	0,91
		Asia Pacific	482	27,0	162	33,6	517	28,4	173	33,5	1,01		Algorithm converged.	0,77	1,31	0,001		Algorithm converged.	-0,057	0,060		1,00		Algorithm converged.	0,84	1,20	0,9606		1,00		Algorithm converged.	0,84	1,19
		Latin America	42	2,4	6	14,3	45	2,5	2	4,4	3,58		Algorithm converged.	0,68	18,85	0,098		Algorithm converged.	-0,023	0,220		3,21		Algorithm converged.	0,69	15,05	0,1383		0,31		Algorithm converged.	0,07	1,46
		Other	183	10,3	27	14,8	184	10,1	13	7,1	2,28		Algorithm converged.	1,13	4,57	0,077		Algorithm converged.	0,014	0,140		2,09		Algorithm converged.	1,11	3,92	0,0218		0,48		Algorithm converged.	0,26	0,90
	DEHYDRATION	USA/Canada	262	14,7	46	17,6	252	13,8	33	13,1	1,41		Algorithm converged.	0,87	2,30	0,045		Algorithm converged.	-0,017	0,107		1,34		Algorithm converged.	0,89	2,02	0,1634	-	0,75		Algorithm converged.	0,49	1,13
		Western Europe	814	45,7	7	0,9	824	45,2	1	0,1	7,14		Algorithm converged.	0,88	58,15	0,007		Algorithm converged.	0,001	0,014		7,09		Algorithm converged.	0,87	57,46	0,0667		0,14		Algorithm converged.	0,02	1,14
		Asia Pacific	482	27,0	6	1,2	517	28,4	3	0,6	2,16		Algorithm converged.	0,54	8,68	0,007		Algorithm converged.	-0,005	0,019		2,15		Algorithm converged.	0,54	8,53	0,2785		0,47		Algorithm converged.	0,12	1,85
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091		1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIABETES MELLITUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIABETIC METABOLIC DECOMPENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSLIPIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROLYTE IMBALANCE	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAILURE TO THRIVE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028		1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
		Western Europe	814	45,7	11	1,4	824	45,2	3	0,4	3,75		Algorithm converged.	1,04	13,49	0,010		Algorithm converged.	0,001	0,019		3,71		Algorithm converged.	1,04	13,26	0,0435		0,27		Algorithm converged.	0,08	0,96
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOLATE DEFICIENCY	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FOOD AVERSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GOUT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOCHROMATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERCALCAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	4	2,2	0,50		Algorithm converged.	0,09	2,75	-0,011		Algorithm converged.	-0,037	0,015	0,50		Algorithm converged.	0,09	2,71	0,4238		1,99		Algorithm converged.	0,37	10,73
	HYPERCHLORAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPERCHOLESTEROLAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103		2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERGLYCAEMIA	USA/Canada	262	14,7	11	4,2	252	13,8	16	6,3	0,65		Algorithm converged.	0,29	1,42	-0,022		Algorithm converged.	-0,060	0,017		0,66		Algorithm converged.	0,31	1,40	0,2784	-	1,51		Algorithm converged.	0,72	3,19	
		Western Europe	814	45,7	1	0,1	824	45,2	10	1,2	0,10		Algorithm converged.	0,01	0,78	-0,011		Algorithm converged.	-0,019	-0,003		0,10		Algorithm converged.	0,01	0,79	0,0288		9,88		Algorithm converged.	1,27	76,99	
		Asia Pacific	482	27,0	9	1,9	517	28,4	5	1,0	1,95		Algorithm converged.	0,65	5,86	0,009		Algorithm converged.	-0,006	0,024		1,93		Algorithm converged.	0,65	5,72	0,2352		0,52		Algorithm converged.	0,17	1,53	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31
	HYPERKALAEMIA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERMAGNESAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002002 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERNATRAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	HYPERPHOSPHATAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.073145893 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERURICAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOALBUMINAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023	1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	USA/Canada	262	14,7	9	3,4	252	13,8	4	1,6	2,21		Algorithm converged.	0,67	7,26	0,018		Algorithm converged.	-0,008	0,045	2,16		Algorithm converged.	0,68	6,94	0,1940	-	0,46		Algorithm converged.	0,14	1,48
		Western Europe	814	45,7	12	1,5	824	45,2	7	0,8	1,75		Algorithm converged.	0,68	4,46	0,006		Algorithm converged.	-0,004	0,017	1,74		Algorithm converged.	0,69	4,39	0,2439		0,58		Algorithm converged.	0,23	1,46
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012	1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812879 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	7	3,8	184	10,1	7	3,8	1,01		Algorithm converged.	0,35	2,93	0,000		Algorithm converged.	-0,039	0,039	1,01		Algorithm converged.	0,36	2,81	0,9917		0,99		Algorithm converged.	0,36	2,78
	HYPOCHLORAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOGLYCAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	USA/Canada	262	14,7	48	18,3	252	13,8	40	15,9	1,19		Algorithm converged.	0,75	1,88	0,024		Algorithm converged.	-0,041	0,090	1,15		Algorithm converged.	0,79	1,69	0,4622	-	0,87		Algorithm converged.	0,59	1,27
		Western Europe	814	45,7	30	3,7	824	45,2	15	1,8	2,06		Algorithm converged.	1,10	3,87	0,019		Algorithm converged.	0,003	0,034	2,02		Algorithm converged.	1,10	3,73	0,0239		0,49		Algorithm converged.	0,27	0,91
		Asia Pacific	482	27,0	23	4,8	517	28,4	23	4,4	1,08		Algorithm converged.	0,60	1,94	0,003		Algorithm converged.	-0,023	0,029	1,07		Algorithm converged.	0,61	1,89	0,8077		0,93		Algorithm converged.	0,53	1,64

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33						
		Other	183	10,3	5	2,7	184	10,1	1	0,5	5,14		Algorithm converged.	0,59	44,44	0,022		Algorithm converged.	-0,004	0,048	5,03		Algorithm converged.	0,59	42,61	0,1386		0,20		Algorithm converged.	0,02	1,69						
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	66	25,2	252	13,8	38	15,1	1,90		Algorithm converged.	1,22	2,96	0,101		Algorithm converged.	0,032	0,170	1,67		Algorithm converged.	1,17	2,39	0,0052	-	0,60		Algorithm converged.	0,42	0,86						
		Western Europe	814	45,7	21	2,6	824	45,2	14	1,7	1,53		Algorithm converged.	0,77	3,03	0,009		Algorithm converged.	-0,005	0,023	1,52		Algorithm converged.	0,78	2,97	0,2213		0,66		Algorithm converged.	0,34	1,29						
		Asia Pacific	482	27,0	12	2,5	517	28,4	8	1,5	1,62		Algorithm converged.	0,66	4,01	0,009		Algorithm converged.	-0,008	0,027	1,61		Algorithm converged.	0,66	3,90	0,2928		0,62		Algorithm converged.	0,26	1,51						
		Latin America	42	2,4	3	7,1	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,092	*	WARNING: The relative Hessian convergence criterion of 4.1442915822 is greater than the limit of 0.0001. The convergence is questionable.	-0,216	0,400	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		Other	183	10,3	5	2,7	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPONATRAEMIA	USA/Canada	262	14,7	5	1,9	252	13,8	10	4,0	0,47		Algorithm converged.	0,16	1,40	-0,021		Algorithm converged.	-0,050	0,009		0,48		Algorithm converged.	0,17	1,39	0,1757	-	2,08		Algorithm converged.	0,72	6,00
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009		1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009		0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002002 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPHAGIA	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	9	3,4	252	13,8	8	3,2	1,08		Algorithm converged.	0,41	2,86	0,003		Algorithm converged.	-0,028	0,034	1,08		Algorithm converged.	0,42	2,76	0,8689	-	0,92		Algorithm converged.	0,36	2,36
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPROTEINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOVOLAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCREASED APPETITE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRON DEFICIENCY	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LACTOSE INTOLERANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAGNESIUM DEFICIENCY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OBESITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYDIPSIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TETANY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TUMOUR LYSIS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TYPE 2 DIABETES MELLITUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105			1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VITAMIN B12 DEFICIENCY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN C DEFICIENCY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN D DEFICIENCY	USA/Canada	262	14,7	4	1,5	252	13,8	6	2,4	0,64		Algorithm converged.	0,18	2,28	-0,009		Algorithm converged.	-0,033	0,015	0,64		Algorithm converged.	0,18	2,25	0,4871	-	1,56		Algorithm converged.	0,45	5,46
		Western Europe	814	45,7	8	1,0	824	45,2	5	0,6	1,63		Algorithm converged.	0,53	4,99	0,004		Algorithm converged.	-0,005	0,012	1,62		Algorithm converged.	0,53	4,93	0,3959		0,62		Algorithm converged.	0,20	1,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	USA/Canada	262	14,7	199	76,0	252	13,8	199	79,0	0,84		Algorithm converged.	0,56	1,27	-0,030		Algorithm converged.	-0,102	0,042	0,96		Algorithm converged.	0,88	1,06	0,4136	0,8512	1,04		Algorithm converged.	0,95	1,14
		Western Europe	814	45,7	549	67,4	824	45,2	583	70,8	0,86		Algorithm converged.	0,69	1,06	-0,033		Algorithm converged.	-0,078	0,012	0,95		Algorithm converged.	0,89	1,02	0,1479		1,05		Algorithm converged.	0,98	1,12
		Asia Pacific	482	27,0	265	55,0	517	28,4	304	58,8	0,86		Algorithm converged.	0,67	1,10	-0,038		Algorithm converged.	-0,100	0,023	0,94		Algorithm converged.	0,84	1,04	0,2240		1,07		Algorithm converged.	0,96	1,19
		Latin America	42	2,4	18	42,9	45	2,5	16	35,6	1,36		Algorithm converged.	0,57	3,22	0,073		Algorithm converged.	-0,132	0,278	1,21		Algorithm converged.	0,71	2,04	0,4865		0,83		Algorithm converged.	0,49	1,40
		Other	183	10,3	85	46,4	184	10,1	83	45,1	1,06		Algorithm converged.	0,70	1,59	0,013		Algorithm converged.	-0,089	0,115	1,03		Algorithm converged.	0,82	1,29	0,7968		0,97		Algorithm converged.	0,78	1,21
	ARTHRALGIA	USA/Canada	262	14,7	103	39,3	252	13,8	119	47,2	0,72		Algorithm converged.	0,51	1,03	-0,079		Algorithm converged.	-0,165	0,006	0,83		Algorithm converged.	0,68	1,02	0,0713	0,7621	1,20		Algorithm converged.	0,98	1,47
		Western Europe	814	45,7	274	33,7	824	45,2	292	35,4	0,92		Algorithm converged.	0,75	1,13	-0,018		Algorithm converged.	-0,064	0,028	0,95		Algorithm converged.	0,83	1,09	0,4500		1,05		Algorithm converged.	0,92	1,20
		Asia Pacific	482	27,0	116	24,1	517	28,4	133	25,7	0,92		Algorithm converged.	0,69	1,22	-0,017		Algorithm converged.	-0,070	0,037	0,94		Algorithm converged.	0,75	1,16	0,5450		1,07		Algorithm converged.	0,86	1,33
		Latin America	42	2,4	8	19,0	45	2,5	7	15,6	1,28		Algorithm converged.	0,42	3,89	0,035		Algorithm converged.	-0,124	0,194	1,22		Algorithm converged.	0,49	3,08	0,6672		0,82		Algorithm converged.	0,32	2,06
		Other	183	10,3	33	18,0	184	10,1	32	17,4	1,05		Algorithm converged.	0,61	1,79	0,006		Algorithm converged.	-0,072	0,085	1,04		Algorithm converged.	0,67	1,61	0,8721		0,96		Algorithm converged.	0,62	1,50
	ARTHRITIS	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021	0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014	1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ARTHROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	AXILLARY MASS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BACK PAIN	USA/Canada	262	14,7	28	10,7	252	13,8	42	16,7	0,60		Algorithm converged.	0,36	1,00	-0,060		Algorithm converged.	-0,119	0,000	0,64		Algorithm converged.	0,41	1,00	0,0507	-	1,56		Algorithm converged.	1,00	2,44	
		Western Europe	814	45,7	77	9,5	824	45,2	76	9,2	1,03		Algorithm converged.	0,74	1,43	0,002		Algorithm converged.	-0,026	0,031	1,03		Algorithm converged.	0,76	1,39	0,8696		0,98		Algorithm converged.	0,72	1,32	
		Asia Pacific	482	27,0	41	8,5	517	28,4	55	10,6	0,78		Algorithm converged.	0,51	1,19	-0,021		Algorithm converged.	-0,058	0,015	0,80		Algorithm converged.	0,54	1,17	0,2547		1,25		Algorithm converged.	0,85	1,84	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	3	7,1	45	2,5	4	8,9	0,79		Algorithm converged.	0,17	3,75	-0,017		Algorithm converged.	-0,131	0,096	0,80		Algorithm converged.	0,19	3,38	0,7654		1,24		Algorithm converged.	0,30	5,23
		Other	183	10,3	7	3,8	184	10,1	6	3,3	1,18		Algorithm converged.	0,39	3,58	0,006		Algorithm converged.	-0,032	0,043	1,17		Algorithm converged.	0,40	3,42	0,7702		0,85		Algorithm converged.	0,29	2,49
	BONE FORMATION INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE PAIN	USA/Canada	262	14,7	43	16,4	252	13,8	58	23,0	0,66		Algorithm converged.	0,42	1,02	-0,066		Algorithm converged.	-0,135	0,003	0,71		Algorithm converged.	0,50	1,02	0,0615	-	1,40		Algorithm converged.	0,98	2,00
		Western Europe	814	45,7	85	10,4	824	45,2	92	11,2	0,93		Algorithm converged.	0,68	1,27	-0,007		Algorithm converged.	-0,037	0,023	0,94		Algorithm converged.	0,71	1,24	0,6376		1,07		Algorithm converged.	0,81	1,41
		Asia Pacific	482	27,0	22	4,6	517	28,4	19	3,7	1,25		Algorithm converged.	0,67	2,35	0,009		Algorithm converged.	-0,016	0,034	1,24		Algorithm converged.	0,68	2,27	0,4799		0,81		Algorithm converged.	0,44	1,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.532081293 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	21	11,5	184	10,1	23	12,5	0,91		Algorithm converged.	0,48	1,70	-0,010		Algorithm converged.	-0,077	0,056		0,92		Algorithm converged.	0,53	1,60	0,7627		1,09		Algorithm converged.	0,63	1,90	
	BURSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST WALL MASS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COCCYDYNIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CONNECTIVE TISSUE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COSTOCHONDRITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DACTYLITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	DUPUYTREN'S CONTRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	EXOSTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FIBROMYALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FLANK PAIN	USA/Canada	262	14,7	3	1,1	252	13,8	6	2,4	0,47		Algorithm converged.	0,12	1,92	-0,012		Algorithm converged.	-0,035	0,010	0,48		Algorithm converged.	0,12	1,90	0,2967	-	2,08		Algorithm converged.	0,53	8,22
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GROIN PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMARTHROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERVERTEBRAL DISC PROTRUSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	JAW CLICKING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT INSTABILITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE		NE		NE	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
	JOINT LOCK	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE		NE		NE	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE
	JOINT NOISE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE		NE	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT RANGE OF MOTION DECREASED	USA/Canada	262	14,7	5	1,9	252	13,8	8	3,2	0,59		Algorithm converged.	0,19	1,84	-0,013		Algorithm converged.	-0,040	0,015	0,60		Algorithm converged.	0,20	1,81	0,3662	-	1,66		Algorithm converged.	0,55	5,02
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	JOINT STIFFNESS	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40
		Asia Pacific	482	27,0	6	1,2	517	28,4	3	0,6	2,16		Algorithm converged.	0,54	8,68	0,007		Algorithm converged.	-0,005	0,019	2,15		Algorithm converged.	0,54	8,53	0,2785		0,47		Algorithm converged.	0,12	1,85
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT SWELLING	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023	1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	5	0,6	824	45,2	7	0,8	0,72		Algorithm converged.	0,23	2,28	-0,002		Algorithm converged.	-0,011	0,006	0,72		Algorithm converged.	0,23	2,27	0,5784		1,38		Algorithm converged.	0,44	4,34
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIMB DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	5	2,0	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	12	1,5	824	45,2	11	1,3	1,11		Algorithm converged.	0,49	2,52	0,001		Algorithm converged.	-0,010	0,013		1,10		Algorithm converged.	0,49	2,49	0,8108		0,91		Algorithm converged.	0,40	2,04
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIMB MASS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE ATROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE RIGIDITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE SPASMS	USA/Canada	262	14,7	44	16,8	252	13,8	26	10,3	1,75		Algorithm converged.	1,04	2,95	0,065		Algorithm converged.	0,006	0,124	1,63		Algorithm converged.	1,03	2,56	0,0350	-	0,61		Algorithm converged.	0,39	0,97
		Western Europe	814	45,7	93	11,4	824	45,2	47	5,7	2,13		Algorithm converged.	1,48	3,07	0,057		Algorithm converged.	0,030	0,084	2,00		Algorithm converged.	1,43	2,81	<.0001		0,50		Algorithm converged.	0,36	0,70
		Asia Pacific	482	27,0	14	2,9	517	28,4	8	1,5	1,90		Algorithm converged.	0,79	4,58	0,014		Algorithm converged.	-0,005	0,032	1,88		Algorithm converged.	0,79	4,43	0,1511		0,53		Algorithm converged.	0,23	1,26
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE TIGHTNESS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE TWITCHING	USA/Canada	262	14,7	8	3,1	252	13,8	4	1,6	1,95		Algorithm converged.	0,58	6,57	0,015		Algorithm converged.	-0,011	0,041	1,92		Algorithm converged.	0,59	6,31	0,2803	-	0,52		Algorithm converged.	0,16	1,70
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULAR WEAKNESS	USA/Canada	262	14,7	10	3,8	252	13,8	10	4,0	0,96		Algorithm converged.	0,39	2,35	-0,002		Algorithm converged.	-0,035	0,032	0,96		Algorithm converged.	0,41	2,27	0,9293	-	1,04		Algorithm converged.	0,44	2,46
		Western Europe	814	45,7	8	1,0	824	45,2	11	1,3	0,73		Algorithm converged.	0,29	1,83	-0,004		Algorithm converged.	-0,014	0,007	0,74		Algorithm converged.	0,30	1,82	0,5074		1,36		Algorithm converged.	0,55	3,36
		Asia Pacific	482	27,0	7	1,5	517	28,4	9	1,7	0,83		Algorithm converged.	0,31	2,25	-0,003		Algorithm converged.	-0,018	0,013	0,83		Algorithm converged.	0,31	2,22	0,7170		1,20		Algorithm converged.	0,45	3,19
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL CHEST PAIN	USA/Canada	262	14,7	17	6,5	252	13,8	19	7,5	0,85		Algorithm converged.	0,43	1,68	-0,011		Algorithm converged.	-0,055	0,034		0,86		Algorithm converged.	0,46	1,62	0,6410	-	1,16		Algorithm converged.	0,62	2,18
		Western Europe	814	45,7	21	2,6	824	45,2	26	3,2	0,81		Algorithm converged.	0,45	1,46	-0,006		Algorithm converged.	-0,022	0,010		0,82		Algorithm converged.	0,46	1,44	0,4863		1,22		Algorithm converged.	0,69	2,16
		Asia Pacific	482	27,0	13	2,7	517	28,4	9	1,7	1,56		Algorithm converged.	0,66	3,69	0,010		Algorithm converged.	-0,009	0,028		1,55		Algorithm converged.	0,67	3,59	0,3074		0,65		Algorithm converged.	0,28	1,50
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL DISCOMFORT	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE				NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE				NE	NE
	MUSCULOSKELETAL PAIN	USA/Canada	262	14,7	5	1,9	252	13,8	11	4,4	0,43		Algorithm converged.	0,15	1,24	-0,025		Algorithm converged.	-0,055	0,006	0,44		Algorithm converged.	0,15	1,24	0,1200	-	2,29		Algorithm converged.	0,81	6,49
		Western Europe	814	45,7	72	8,8	824	45,2	76	9,2	0,96		Algorithm converged.	0,68	1,34	-0,004		Algorithm converged.	-0,032	0,024	0,96		Algorithm converged.	0,71	1,30	0,7896		1,04		Algorithm converged.	0,77	1,42
		Asia Pacific	482	27,0	14	2,9	517	28,4	23	4,4	0,64		Algorithm converged.	0,33	1,26	-0,015		Algorithm converged.	-0,039	0,008	0,65		Algorithm converged.	0,34	1,25	0,2005		1,53		Algorithm converged.	0,80	2,94
		Latin America	42	2,4	1	2,4	45	2,5	3	6,7	0,34		Algorithm converged.	0,03	3,42	-0,043		Algorithm converged.	-0,129	0,043	0,36		Algorithm converged.	0,04	3,30	0,3642		2,80		Algorithm converged.	0,30	25,88
		Other	183	10,3	11	6,0	184	10,1	12	6,5	0,92		Algorithm converged.	0,39	2,13	-0,005		Algorithm converged.	-0,055	0,044	0,92		Algorithm converged.	0,42	2,04	0,8401		1,08		Algorithm converged.	0,49	2,40
	MUSCULOSKELETAL STIFFNESS	USA/Canada	262	14,7	0	0,0	252	13,8	7	2,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	7	0,9	824	45,2	10	1,2	0,71		Algorithm converged.	0,27	1,86	-0,004		Algorithm converged.	-0,013	0,006	0,71		Algorithm converged.	0,27	1,85	0,4823		1,41		Algorithm converged.	0,54	3,69
		Asia Pacific	482	27,0	10	2,1	517	28,4	14	2,7	0,76		Algorithm converged.	0,33	1,73	-0,006		Algorithm converged.	-0,025	0,013	0,77		Algorithm converged.	0,34	1,71	0,5150		1,31		Algorithm converged.	0,59	2,91
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	MYALGIA	USA/Canada	262	14,7	79	30,2	252	13,8	82	32,5	0,89		Algorithm converged.	0,62	1,30	-0,024		Algorithm converged.	-0,104	0,056	0,93		Algorithm converged.	0,72	1,20	0,5598	-	1,08		Algorithm converged.	0,84	1,39
		Western Europe	814	45,7	210	25,8	824	45,2	269	32,6	0,72		Algorithm converged.	0,58	0,89	-0,068		Algorithm converged.	-0,112	-0,025	0,79		Algorithm converged.	0,68	0,92	0,0024		1,27		Algorithm converged.	1,09	1,47
		Asia Pacific	482	27,0	141	29,3	517	28,4	158	30,6	0,94		Algorithm converged.	0,72	1,23	-0,013		Algorithm converged.	-0,070	0,044	0,96		Algorithm converged.	0,79	1,16	0,6521		1,04		Algorithm converged.	0,86	1,26
		Latin America	42	2,4	2	4,8	45	2,5	3	6,7	0,70		Algorithm converged.	0,11	4,41	-0,019		Algorithm converged.	-0,116	0,078	0,71		Algorithm converged.	0,13	4,07	0,7045		1,40		Algorithm converged.	0,25	7,97
		Other	183	10,3	29	15,8	184	10,1	16	8,7	1,98		Algorithm converged.	1,03	3,78	0,072		Algorithm converged.	0,005	0,138	1,82		Algorithm converged.	1,03	3,24	0,0408		0,55		Algorithm converged.	0,31	0,98
	MYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NECK PAIN	USA/Canada	262	14,7	7	2,7	252	13,8	10	4,0	0,66		Algorithm converged.	0,25	1,77	-0,013		Algorithm converged.	-0,044	0,018	0,67		Algorithm converged.	0,26	1,74	0,4145	-	1,49		Algorithm converged.	0,57	3,84
		Western Europe	814	45,7	19	2,3	824	45,2	16	1,9	1,21		Algorithm converged.	0,62	2,36	0,004		Algorithm converged.	-0,010	0,018	1,20		Algorithm converged.	0,62	2,32	0,5835		0,83		Algorithm converged.	0,43	1,61
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014	1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.397994570 2 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	OSTEOARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40	
		Asia Pacific	482	27,0	5	1,0	517	28,4	4	0,8	1,34		Algorithm converged.	0,36	5,04	0,003		Algorithm converged.	-0,009	0,014	1,34		Algorithm converged.	0,36	4,96	0,6606		0,75		Algorithm converged.	0,20	2,76	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OSTEONECROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OSTEOPENIA	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033		1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	14	1,7	824	45,2	6	0,7	2,39		Algorithm converged.	0,91	6,24	0,010		Algorithm converged.	-0,001	0,021		2,36		Algorithm converged.	0,91	6,12	0,0766		0,42		Algorithm converged.	0,16	1,10
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OSTEOPOROSIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	17	2,1	824	45,2	10	1,2	1,74		Algorithm converged.	0,79	3,81	0,009		Algorithm converged.	-0,004	0,021	1,72		Algorithm converged.	0,79	3,74	0,1698		0,58		Algorithm converged.	0,27	1,26
		Asia Pacific	482	27,0	9	1,9	517	28,4	10	1,9	0,96		Algorithm converged.	0,39	2,39	-0,001		Algorithm converged.	-0,018	0,016	0,97		Algorithm converged.	0,40	2,36	0,9382		1,04		Algorithm converged.	0,42	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAIN IN EXTREMITY	USA/Canada	262	14,7	40	15,3	252	13,8	49	19,4	0,75		Algorithm converged.	0,47	1,18	-0,042		Algorithm converged.	-0,107	0,024	0,79		Algorithm converged.	0,54	1,15	0,2124	-	1,27		Algorithm converged.	0,87	1,86
		Western Europe	814	45,7	96	11,8	824	45,2	101	12,3	0,96		Algorithm converged.	0,71	1,29	-0,005		Algorithm converged.	-0,036	0,027	0,96		Algorithm converged.	0,74	1,25	0,7730		1,04		Algorithm converged.	0,80	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	28	5,8	517	28,4	37	7,2	0,80		Algorithm converged.	0,48	1,33	-0,013		Algorithm converged.	-0,044	0,017		0,81		Algorithm converged.	0,50	1,31	0,3893		1,23		Algorithm converged.	0,77	1,98
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	16	8,7	184	10,1	15	8,2	1,08		Algorithm converged.	0,52	2,25	0,006		Algorithm converged.	-0,051	0,063		1,07		Algorithm converged.	0,55	2,10	0,8387		0,93		Algorithm converged.	0,48	1,83
	PAIN IN JAW	USA/Canada	262	14,7	1	0,4	252	13,8	7	2,8	0,13		Algorithm converged.	0,02	1,10	-0,024		Algorithm converged.	-0,046	-0,002		0,14		Algorithm converged.	0,02	1,11	0,0625	-	7,28		Algorithm converged.	0,90	58,73
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008		2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	4	0,8	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	0,031	*	WARNING: The relative Hessian convergence criterion of 18.885863102 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,121	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PERIOSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLANTAR FASCIITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POLYARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSORIATIC ARTHROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	RHEUMATOID ARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ROTATOR CUFF SYNDROME	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SACRAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SACROILIITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SJOGREN'S SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL OSTEOARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SPINAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	8	1,0	824	45,2	7	0,8	1,16		Algorithm converged.	0,42	3,21	0,001		Algorithm converged.	-0,008	0,011	1,16		Algorithm converged.	0,42	3,18	0,7773		0,86		Algorithm converged.	0,31	2,37
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	SPINAL STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SYNOVIAL CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SYSTEMIC LUPUS ERYTHEMATOSUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TEMPOROMANDIBULAR JOINT SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDINOUS CONTRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDON DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDON PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENDONITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	6	0,7	824	45,2	7	0,8	0,87		Algorithm converged.	0,29	2,59	-0,001		Algorithm converged.	-0,010	0,007	0,87		Algorithm converged.	0,29	2,57	0,7978		1,15		Algorithm converged.	0,39	3,41
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TENOSYNOVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	TENOSYNOVITIS STENOSANS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	TORTICOLLIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	TRIGGER FINGER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRISMUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WINGED SCAPULA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	8	3,2	0,47		Algorithm converged.	0,14	1,59	-0,016		Algorithm converged.	-0,043	0,010		0,48		Algorithm converged.	0,15	1,58	0,2270	-		2,08		Algorithm converged.	0,63	6,82
		Western Europe	814	45,7	10	1,2	824	45,2	17	2,1	0,59		Algorithm converged.	0,27	1,30	-0,008		Algorithm converged.	-0,021	0,004		0,60		Algorithm converged.	0,27	1,29	0,1899			1,68		Algorithm converged.	0,77	3,65
		Asia Pacific	482	27,0	4	0,8	517	28,4	9	1,7	0,47		Algorithm converged.	0,14	1,54	-0,009		Algorithm converged.	-0,023	0,005		0,48		Algorithm converged.	0,15	1,54	0,2151			2,10		Algorithm converged.	0,65	6,77
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103		2,14		Algorithm converged.	0,20	22,77	0,5273			0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021		1,01		Algorithm converged.	0,14	7,06	0,9956			0,99		Algorithm converged.	0,14	6,99
	ACROCHORDON	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	ACUTE MYELOID LEUKAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANOGENITAL WARTS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BASAL CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BENIGN BREAST NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BENIGN NEOPLASM OF LACRIMAL DUCT	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CANCER FATIGUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID TUMOUR	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FIBROADENOMA OF BREAST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FIBROMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMANGIOMA OF LIVER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERGAMMAGLOBULINAEMIA BENIGN MONOCLONAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LENTIGO MALIGNA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	LOBULAR BREAST CARCINOMA IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MELANOCYTIC NAEVUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENINGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MONOCLONAL GAMMOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYELODYSPLASTIC SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAEVUS HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURILEMMOMA BENIGN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FIBROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OVARIAN GERM CELL TERATOMA BENIGN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLARY THYROID CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARATHYROID TUMOUR BENIGN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PELVIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PYOGENIC GRANULOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SEBORRHOEIC KERATOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SKIN PAPILLOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	SMALL CELL LUNG CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	SQUAMOUS CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TUMOUR PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	UTERINE LEIOMYOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00	
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	233	88,9	252	13,8	226	89,7	0,92		Algorithm converged.	0,53	1,62	-0,008		Algorithm converged.	-0,061	0,046		0,99		Algorithm converged.	0,93	1,05	0,7829	0,3560	1,01		Algorithm converged.	0,95	1,07	
		Western Europe	814	45,7	615	75,6	824	45,2	583	70,8	1,28		Algorithm converged.	1,03	1,59	0,048		Algorithm converged.	0,005	0,091		1,07		Algorithm converged.	1,01	1,13	0,0286		0,94		Algorithm converged.	0,88	0,99	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	295	61,2	517	28,4	313	60,5	1,03		Algorithm converged.	0,80	1,33	0,007		Algorithm converged.	-0,054	0,067		1,01		Algorithm converged.	0,92	1,12	0,8304		0,99		Algorithm converged.	0,90	1,09
		Latin America	42	2,4	24	57,1	45	2,5	23	51,1	1,28		Algorithm converged.	0,55	2,97	0,060		Algorithm converged.	-0,149	0,269		1,12		Algorithm converged.	0,76	1,65	0,5727		0,89		Algorithm converged.	0,61	1,32
		Other	183	10,3	88	48,1	184	10,1	76	41,3	1,32		Algorithm converged.	0,87	1,99	0,068		Algorithm converged.	-0,034	0,169		1,16		Algorithm converged.	0,93	1,46	0,1927		0,86		Algorithm converged.	0,68	1,08
	AGEUSIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	10	1,2	824	45,2	10	1,2	1,01		Algorithm converged.	0,42	2,45	0,000		Algorithm converged.	-0,010	0,011		1,01		Algorithm converged.	0,42	2,42	0,9781		0,99		Algorithm converged.	0,41	2,36
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AKATHISIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLODYNIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AMNESIA	USA/Canada	262	14,7	3	1,1	252	13,8	5	2,0	0,57		Algorithm converged.	0,14	2,42	-0,008		Algorithm converged.	-0,030	0,013	0,58		Algorithm converged.	0,14	2,39	0,4483	-	1,73		Algorithm converged.	0,42	7,18
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANOSMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATAXIA	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AUDITORY NERVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BALANCE DISORDER	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BELL'S PALSY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRACHIAL PLEXOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURNING SENSATION	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028	3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CAROTID ARTERY STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARPAL TUNNEL SYNDROME	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBELLAR SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	CERVICAL RADICULOPATHY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-			Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	CERVICOBRACHIAL SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLONUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	COGNITIVE DISORDER	USA/Canada	262	14,7	9	3,4	252	13,8	9	3,6	0,96		Algorithm converged.	0,37	2,46	-0,001		Algorithm converged.	-0,033	0,030		0,96		Algorithm converged.	0,39	2,38	0,9330	-		1,04		Algorithm converged.	0,42	2,58
		Western Europe	814	45,7	6	0,7	824	45,2	3	0,4	2,03		Algorithm converged.	0,51	8,15	0,004		Algorithm converged.	-0,003	0,011		2,02		Algorithm converged.	0,51	8,07	0,3173			0,49		Algorithm converged.	0,12	1,97
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COMPLEX REGIONAL PAIN SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	COORDINATION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DEMENTIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSED LEVEL OF CONSCIOUSNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISTURBANCE IN ATTENTION	USA/Canada	262	14,7	5	1,9	252	13,8	5	2,0	0,96		Algorithm converged.	0,27	3,36	-0,001		Algorithm converged.	-0,025	0,023	0,96		Algorithm converged.	0,28	3,28	0,9505	-	1,04		Algorithm converged.	0,30	3,55
		Western Europe	814	45,7	14	1,7	824	45,2	10	1,2	1,42		Algorithm converged.	0,63	3,23	0,005		Algorithm converged.	-0,007	0,017	1,42		Algorithm converged.	0,63	3,17	0,3963		0,71		Algorithm converged.	0,32	1,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIZZINESS	USA/Canada	262	14,7	43	16,4	252	13,8	58	23,0	0,66		Algorithm converged.	0,42	1,02	-0,066		Algorithm converged.	-0,135	0,003	0,71		Algorithm converged.	0,50	1,02	0,0615	-	1,40		Algorithm converged.	0,98	2,00
		Western Europe	814	45,7	68	8,4	824	45,2	61	7,4	1,14		Algorithm converged.	0,80	1,63	0,010		Algorithm converged.	-0,017	0,036	1,13		Algorithm converged.	0,81	1,57	0,4753		0,89		Algorithm converged.	0,64	1,23
		Asia Pacific	482	27,0	85	17,6	517	28,4	77	14,9	1,22		Algorithm converged.	0,87	1,71	0,027		Algorithm converged.	-0,018	0,073	1,18		Algorithm converged.	0,89	1,57	0,2408		0,84		Algorithm converged.	0,64	1,12
		Latin America	42	2,4	4	9,5	45	2,5	4	8,9	1,08		Algorithm converged.	0,25	4,62	0,006		Algorithm converged.	-0,115	0,128	1,07		Algorithm converged.	0,29	4,01	0,9184		0,93		Algorithm converged.	0,25	3,50
		Other	183	10,3	15	8,2	184	10,1	10	5,4	1,55		Algorithm converged.	0,68	3,55	0,028		Algorithm converged.	-0,024	0,079	1,51		Algorithm converged.	0,70	3,27	0,2978		0,66		Algorithm converged.	0,31	1,44
	DIZZINESS POSTURAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSAESTHESIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	21	2,6	824	45,2	16	1,9	1,34		Algorithm converged.	0,69	2,58	0,006		Algorithm converged.	-0,008	0,021	1,33		Algorithm converged.	0,70	2,53	0,3865		0,75		Algorithm converged.	0,40	1,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSARTHRIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSGEUSIA	USA/Canada	262	14,7	47	17,9	252	13,8	39	15,5	1,19		Algorithm converged.	0,75	1,90	0,025		Algorithm converged.	-0,040	0,089	1,16		Algorithm converged.	0,79	1,71	0,4554	-	0,86		Algorithm converged.	0,59	1,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	154	18,9	824	45,2	132	16,0	1,22		Algorithm converged.	0,95	1,58	0,029		Algorithm converged.	-0,008	0,066		1,18		Algorithm converged.	0,96	1,46	0,1229		0,85		Algorithm converged.	0,69	1,05
		Asia Pacific	482	27,0	90	18,7	517	28,4	79	15,3	1,27		Algorithm converged.	0,91	1,77	0,034		Algorithm converged.	-0,013	0,081		1,22		Algorithm converged.	0,93	1,61	0,1539		0,82		Algorithm converged.	0,62	1,08
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812879 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	13	7,1	184	10,1	7	3,8	1,93		Algorithm converged.	0,75	4,96	0,033		Algorithm converged.	-0,013	0,079		1,87		Algorithm converged.	0,76	4,57	0,1718		0,54		Algorithm converged.	0,22	1,31
	DYSKINESIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTRIC SHOCK SENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ESSENTIAL TREMOR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	FACIAL NERVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE CONVULSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FORMICATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HEAD DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAD TITUBATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	USA/Canada	262	14,7	85	32,4	252	13,8	98	38,9	0,75		Algorithm converged.	0,53	1,08	-0,064		Algorithm converged.	-0,147	0,018	0,83		Algorithm converged.	0,66	1,05	0,1281	0,4572	1,20		Algorithm converged.	0,95	1,51
		Western Europe	814	45,7	174	21,4	824	45,2	187	22,7	0,93		Algorithm converged.	0,73	1,17	-0,013		Algorithm converged.	-0,053	0,027	0,94		Algorithm converged.	0,78	1,13	0,5200		1,06		Algorithm converged.	0,88	1,27
		Asia Pacific	482	27,0	90	18,7	517	28,4	90	17,4	1,09		Algorithm converged.	0,79	1,50	0,013		Algorithm converged.	-0,035	0,060	1,07		Algorithm converged.	0,82	1,40	0,6035		0,93		Algorithm converged.	0,72	1,21
		Latin America	42	2,4	9	21,4	45	2,5	14	31,1	0,60		Algorithm converged.	0,23	1,59	-0,097		Algorithm converged.	-0,280	0,087	0,69		Algorithm converged.	0,33	1,42	0,3129		1,45		Algorithm converged.	0,70	3,00
		Other	183	10,3	40	21,9	184	10,1	35	19,0	1,19		Algorithm converged.	0,72	1,98	0,028		Algorithm converged.	-0,054	0,111	1,15		Algorithm converged.	0,77	1,72	0,5011		0,87		Algorithm converged.	0,58	1,30
	HEMIANOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERAESTHESIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	1	0,1	824	45,2	6	0,7	0,17		Algorithm converged.	0,02	1,40	-0,006		Algorithm converged.	-0,012	0,000	0,17		Algorithm converged.	0,02	1,40	0,0991		5,93		Algorithm converged.	0,72	49,12
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERGEUSIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPATHIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERSOMNIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOAESTHESIA	USA/Canada	262	14,7	17	6,5	252	13,8	12	4,8	1,39		Algorithm converged.	0,65	2,97	0,017		Algorithm converged.	-0,022	0,057	1,36		Algorithm converged.	0,66	2,80	0,3987	-	0,73		Algorithm converged.	0,36	1,51

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	10	1,2	824	45,2	17	2,1	0,59		Algorithm converged.	0,27	1,30	-0,008		Algorithm converged.	-0,021	0,004		0,60		Algorithm converged.	0,27	1,29	0,1899		1,68		Algorithm converged.	0,77	3,65
		Asia Pacific	482	27,0	30	6,2	517	28,4	31	6,0	1,04		Algorithm converged.	0,62	1,75	0,002		Algorithm converged.	-0,027	0,032		1,04		Algorithm converged.	0,64	1,69	0,8805		0,96		Algorithm converged.	0,59	1,57
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	8	4,4	184	10,1	3	1,6	2,76		Algorithm converged.	0,72	10,57	0,027		Algorithm converged.	-0,007	0,062		2,68		Algorithm converged.	0,72	9,95	0,1404		0,37		Algorithm converged.	0,10	1,38
	HYPOGEUSIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPOSMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOTONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERCOSTAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LACUNAR INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LETHARGY	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	12	1,5	824	45,2	13	1,6	0,93		Algorithm converged.	0,42	2,06	-0,001		Algorithm converged.	-0,013	0,011		0,93		Algorithm converged.	0,43	2,04	0,8644		1,07		Algorithm converged.	0,49	2,33
		Asia Pacific	482	27,0	4	0,8	517	28,4	11	2,1	0,38		Algorithm converged.	0,12	1,22	-0,013		Algorithm converged.	-0,028	0,002		0,39		Algorithm converged.	0,13	1,22	0,1048		2,56		Algorithm converged.	0,82	8,00
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	1	0,5	4,09		Algorithm converged.	0,45	36,94	0,016		Algorithm converged.	-0,007	0,040		4,02		Algorithm converged.	0,45	35,64	0,2112		0,25		Algorithm converged.	0,03	2,20
	LOSS OF CONSCIOUSNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MEMORY IMPAIRMENT	USA/Canada	262	14,7	11	4,2	252	13,8	10	4,0	1,06		Algorithm converged.	0,44	2,54	0,002		Algorithm converged.	-0,032	0,037		1,06		Algorithm converged.	0,46	2,45	0,8952	-	0,95		Algorithm converged.	0,41	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	15	1,8	824	45,2	8	1,0	1,91		Algorithm converged.	0,81	4,54	0,009		Algorithm converged.	-0,003	0,020	1,90		Algorithm converged.	0,81	4,45	0,1407		0,53		Algorithm converged.	0,22	1,24
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	MENTAL IMPAIRMENT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIGRAINE	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016	0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	8	1,0	824	45,2	2	0,2	4,08		Algorithm converged.	0,86	19,27	0,007		Algorithm converged.	0,000	0,015	4,05		Algorithm converged.	0,86	19,01	0,0763		0,25		Algorithm converged.	0,05	1,16
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MIGRAINE WITH AURA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MORTON'S NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTIONS INVOLUNTARY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE SPASTICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NERVE COMPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURALGIA	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010	0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	11	1,4	824	45,2	13	1,6	0,85		Algorithm converged.	0,38	1,92	-0,002		Algorithm converged.	-0,014	0,009	0,86		Algorithm converged.	0,39	1,90	0,7034		1,17		Algorithm converged.	0,53	2,59
		Asia Pacific	482	27,0	7	1,5	517	28,4	2	0,4	3,79		Algorithm converged.	0,78	18,36	0,011		Algorithm converged.	-0,001	0,023	3,75		Algorithm converged.	0,78	17,98	0,0979		0,27		Algorithm converged.	0,06	1,28
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	USA/Canada	262	14,7	100	38,2	252	13,8	78	31,0	1,38		Algorithm converged.	0,96	1,98	0,072		Algorithm converged.	-0,010	0,154	1,23		Algorithm converged.	0,97	1,57	0,0875	0,3283	0,81		Algorithm converged.	0,64	1,03
		Western Europe	814	45,7	119	14,6	824	45,2	116	14,1	1,05		Algorithm converged.	0,79	1,38	0,005		Algorithm converged.	-0,029	0,039	1,04		Algorithm converged.	0,82	1,32	0,7546		0,96		Algorithm converged.	0,76	1,22
		Asia Pacific	482	27,0	45	9,3	517	28,4	48	9,3	1,01		Algorithm converged.	0,66	1,54	0,001		Algorithm converged.	-0,036	0,037	1,01		Algorithm converged.	0,68	1,48	0,9776		0,99		Algorithm converged.	0,68	1,46
		Latin America	42	2,4	8	19,0	45	2,5	6	13,3	1,53		Algorithm converged.	0,48	4,85	0,057		Algorithm converged.	-0,098	0,212	1,43		Algorithm converged.	0,54	3,77	0,4717		0,70		Algorithm converged.	0,26	1,85
		Other	183	10,3	12	6,6	184	10,1	20	10,9	0,58		Algorithm converged.	0,27	1,21	-0,043		Algorithm converged.	-0,101	0,014	0,60		Algorithm converged.	0,30	1,20	0,1486		1,66		Algorithm converged.	0,83	3,29

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	32	3,9	824	45,2	34	4,1	0,95		Algorithm converged.	0,58	1,56	-0,002		Algorithm converged.	-0,021	0,017		0,95		Algorithm converged.	0,59	1,53	0,8410		1,05		Algorithm converged.	0,65	1,68
		Asia Pacific	482	27,0	7	1,5	517	28,4	5	1,0	1,51		Algorithm converged.	0,48	4,79	0,005		Algorithm converged.	-0,009	0,018		1,50		Algorithm converged.	0,48	4,70	0,4849		0,67		Algorithm converged.	0,21	2,08
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OCCIPITAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OPHTHALMIC MIGRAINE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORTHOSTATIC INTOLERANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	USA/Canada	262	14,7	24	9,2	252	13,8	29	11,5	0,78		Algorithm converged.	0,44	1,37	-0,023		Algorithm converged.	-0,076	0,029	0,80		Algorithm converged.	0,48	1,33	0,3829	-	1,26		Algorithm converged.	0,75	2,10
		Western Europe	814	45,7	144	17,7	824	45,2	121	14,7	1,25		Algorithm converged.	0,96	1,63	0,030		Algorithm converged.	-0,006	0,066	1,20		Algorithm converged.	0,97	1,50	0,0993		0,83		Algorithm converged.	0,67	1,04
		Asia Pacific	482	27,0	14	2,9	517	28,4	28	5,4	0,52		Algorithm converged.	0,27	1,00	-0,025		Algorithm converged.	-0,050	-0,001	0,54		Algorithm converged.	0,29	1,01	0,0524		1,86		Algorithm converged.	0,99	3,50
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138	3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88
		Other	183	10,3	15	8,2	184	10,1	9	4,9	1,74		Algorithm converged.	0,74	4,07	0,033		Algorithm converged.	-0,017	0,084	1,68		Algorithm converged.	0,75	3,73	0,2063		0,60		Algorithm converged.	0,27	1,33
	PAROSMIA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	8	1,0	824	45,2	4	0,5	2,03		Algorithm converged.	0,61	6,78	0,005		Algorithm converged.	-0,003	0,013	2,02		Algorithm converged.	0,61	6,70	0,2478		0,49		Algorithm converged.	0,15	1,63
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL MOTOR NEUROPATHY	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023		1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	8	1,0	824	45,2	10	1,2	0,81		Algorithm converged.	0,32	2,06	-0,002		Algorithm converged.	-0,012	0,008		0,81		Algorithm converged.	0,32	2,04	0,6548		1,23		Algorithm converged.	0,49	3,11
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL PARALYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL SENSORY NEUROPATHY	USA/Canada	262	14,7	68	26,0	252	13,8	82	32,5	0,73		Algorithm converged.	0,50	1,06	-0,066		Algorithm converged.	-0,144	0,013		0,80		Algorithm converged.	0,61	1,05	0,1019	-	1,25		Algorithm converged.	0,96	1,64
		Western Europe	814	45,7	125	15,4	824	45,2	105	12,7	1,24		Algorithm converged.	0,94	1,64	0,026		Algorithm converged.	-0,008	0,060		1,21		Algorithm converged.	0,95	1,53	0,1287		0,83		Algorithm converged.	0,65	1,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	112	23,2	517	28,4	118	22,8	1,02		Algorithm converged.	0,76	1,37	0,004		Algorithm converged.	-0,048	0,056	1,02		Algorithm converged.	0,81	1,28	0,8770		0,98		Algorithm converged.	0,78	1,23
		Latin America	42	2,4	2	4,8	45	2,5	4	8,9	0,51		Algorithm converged.	0,09	2,96	-0,041		Algorithm converged.	-0,146	0,064	0,54		Algorithm converged.	0,10	2,77	0,4569		1,87		Algorithm converged.	0,36	9,67
		Other	183	10,3	13	7,1	184	10,1	13	7,1	1,01		Algorithm converged.	0,45	2,23	0,000		Algorithm converged.	-0,052	0,053	1,01		Algorithm converged.	0,48	2,11	0,9885		0,99		Algorithm converged.	0,47	2,09
	PHANTOM LIMB SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POLYNEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	40	4,9	824	45,2	39	4,7	1,04		Algorithm converged.	0,66	1,63	0,002		Algorithm converged.	-0,019	0,023	1,04		Algorithm converged.	0,68	1,60	0,8643		0,96		Algorithm converged.	0,63	1,48
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRESYNCOPE	USA/Canada	262	14,7	3	1,1	252	13,8	6	2,4	0,47		Algorithm converged.	0,12	1,92	-0,012		Algorithm converged.	-0,035	0,010	0,48		Algorithm converged.	0,12	1,90	0,2967	-	2,08		Algorithm converged.	0,53	8,22
		Western Europe	814	45,7	8	1,0	824	45,2	8	1,0	1,01		Algorithm converged.	0,38	2,71	0,000		Algorithm converged.	-0,009	0,010	1,01		Algorithm converged.	0,38	2,68	0,9804		0,99		Algorithm converged.	0,37	2,62
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOGENIC SEIZURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOMOTOR HYPERACTIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYRAMIDAL TRACT SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESTLESS LEGS SYNDROME	USA/Canada	262	14,7	4	1,5	252	13,8	5	2,0	0,77		Algorithm converged.	0,20	2,89	-0,005		Algorithm converged.	-0,027	0,018	0,77		Algorithm converged.	0,21	2,83	0,6935	-	1,30		Algorithm converged.	0,35	4,78
		Western Europe	814	45,7	7	0,9	824	45,2	2	0,2	3,57		Algorithm converged.	0,74	17,21	0,006		Algorithm converged.	-0,001	0,013	3,54		Algorithm converged.	0,74	17,00	0,1139		0,28		Algorithm converged.	0,06	1,35
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCIATICA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010	1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEIZURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SENSORY DISTURBANCE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SENSORY LOSS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOMNOLENCE	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008		2,02		Algorithm converged.	0,37	11,02	0,4146			0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	10	2,1	517	28,4	7	1,4	1,54		Algorithm converged.	0,58	4,09	0,007		Algorithm converged.	-0,009	0,023		1,53		Algorithm converged.	0,59	3,99	0,3825			0,65		Algorithm converged.	0,25	1,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	USA/Canada	262	14,7	7	2,7	252	13,8	9	3,6	0,74		Algorithm converged.	0,27	2,02	-0,009		Algorithm converged.	-0,039	0,021	0,75		Algorithm converged.	0,28	1,98	0,5586	-	1,34		Algorithm converged.	0,51	3,53
		Western Europe	814	45,7	16	2,0	824	45,2	5	0,6	3,28		Algorithm converged.	1,20	9,01	0,014		Algorithm converged.	0,003	0,024	3,24		Algorithm converged.	1,19	8,80	0,0212		0,31		Algorithm converged.	0,11	0,84
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.532081298 1 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034		1,34		Algorithm converged.	0,30	5,91	0,6984		0,75		Algorithm converged.	0,17	3,29
	TASTE DISORDER	USA/Canada	262	14,7	64	24,4	252	13,8	49	19,4	1,34		Algorithm converged.	0,88	2,04	0,050		Algorithm converged.	-0,022	0,121		1,26		Algorithm converged.	0,90	1,75	0,1746	-	0,80		Algorithm converged.	0,57	1,11
		Western Europe	814	45,7	65	8,0	824	45,2	48	5,8	1,40		Algorithm converged.	0,95	2,06	0,022		Algorithm converged.	-0,003	0,046		1,37		Algorithm converged.	0,96	1,97	0,0861		0,73		Algorithm converged.	0,51	1,05
		Asia Pacific	482	27,0	12	2,5	517	28,4	21	4,1	0,60		Algorithm converged.	0,29	1,24	-0,016		Algorithm converged.	-0,038	0,006		0,61		Algorithm converged.	0,30	1,23	0,1695		1,63		Algorithm converged.	0,81	3,28
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	8	4,4	184	10,1	6	3,3	1,36		Algorithm converged.	0,46	3,99	0,011		Algorithm converged.	-0,028	0,050		1,34		Algorithm converged.	0,47	3,79	0,5801		0,75		Algorithm converged.	0,26	2,11
	TENSION HEADACHE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THALAMIC INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC NEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TREMOR	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRIGEMINAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ENCEPHALOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOCAL CORD PARESIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
PRODUCT ISSUE	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023		1,28		Algorithm converged.	0,29	5,67	0,7430	-		0,78		Algorithm converged.	0,18	3,45	
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463			2,96		Algorithm converged.	0,31	28,43	
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326			0,47		Algorithm converged.	0,04	5,12	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	DEVICE BREAKAGE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE CONNECTION ISSUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DEFECTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DEVICE DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE ISSUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE MALFUNCTION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE OCCLUSION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS IN DEVICE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	121	46,2	252	13,8	116	46,0	1,01		Algorithm converged.	0,71	1,42	0,002		Algorithm converged.	-0,085	0,088		1,00		Algorithm converged.	0,83	1,21	0,9725	-	1,00		Algorithm converged.	0,83	1,20
		Western Europe	814	45,7	221	27,1	824	45,2	208	25,2	1,10		Algorithm converged.	0,89	1,38	0,019		Algorithm converged.	-0,024	0,062		1,08		Algorithm converged.	0,91	1,27	0,3803		0,93		Algorithm converged.	0,79	1,09
		Asia Pacific	482	27,0	108	22,4	517	28,4	103	19,9	1,16		Algorithm converged.	0,86	1,57	0,025		Algorithm converged.	-0,026	0,076		1,12		Algorithm converged.	0,88	1,43	0,3367		0,89		Algorithm converged.	0,70	1,13
		Latin America	42	2,4	3	7,1	45	2,5	6	13,3	0,50		Algorithm converged.	0,12	2,14	-0,062		Algorithm converged.	-0,188	0,064		0,54		Algorithm converged.	0,14	2,01	0,3543		1,87		Algorithm converged.	0,50	6,99
		Other	183	10,3	26	14,2	184	10,1	24	13,0	1,10		Algorithm converged.	0,61	2,01	0,012		Algorithm converged.	-0,059	0,082		1,09		Algorithm converged.	0,65	1,82	0,7452		0,92		Algorithm converged.	0,55	1,54
	ADJUSTMENT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADJUSTMENT DISORDER WITH DEPRESSED MOOD	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AFFECT LABILITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AFFECTIVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AGITATION	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	AGORAPHOBIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANXIETY	USA/Canada	262	14,7	35	13,4	252	13,8	22	8,7	1,61		Algorithm converged.	0,92	2,83	0,046		Algorithm converged.	-0,008	0,100		1,53		Algorithm converged.	0,92	2,53	0,0984	-	0,65		Algorithm converged.	0,39	1,08
		Western Europe	814	45,7	56	6,9	824	45,2	35	4,2	1,67		Algorithm converged.	1,08	2,57	0,026		Algorithm converged.	0,004	0,049		1,62		Algorithm converged.	1,07	2,44	0,0215		0,62		Algorithm converged.	0,41	0,93
		Asia Pacific	482	27,0	11	2,3	517	28,4	16	3,1	0,73		Algorithm converged.	0,34	1,59	-0,008		Algorithm converged.	-0,028	0,012		0,74		Algorithm converged.	0,35	1,57	0,4307		1,36		Algorithm converged.	0,64	2,89
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091		1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	5	2,7	184	10,1	2	1,1	2,56		Algorithm converged.	0,49	13,35	0,016		Algorithm converged.	-0,012	0,044		2,51		Algorithm converged.	0,49	12,79	0,2668		0,40		Algorithm converged.	0,08	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANXIETY DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONFUSIONAL STATE	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.997887329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DELUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSED MOOD	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	12	1,5	824	45,2	10	1,2	1,22		Algorithm converged.	0,52	2,83	0,003		Algorithm converged.	-0,009	0,014	1,21		Algorithm converged.	0,53	2,80	0,6474		0,82		Algorithm converged.	0,36	1,89
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	USA/Canada	262	14,7	31	11,8	252	13,8	32	12,7	0,92		Algorithm converged.	0,54	1,56	-0,009		Algorithm converged.	-0,065	0,048	0,93		Algorithm converged.	0,59	1,48	0,7647	-	1,07		Algorithm converged.	0,68	1,70
		Western Europe	814	45,7	36	4,4	824	45,2	31	3,8	1,18		Algorithm converged.	0,72	1,93	0,007		Algorithm converged.	-0,013	0,026	1,18		Algorithm converged.	0,73	1,88	0,5003		0,85		Algorithm converged.	0,53	1,36
		Asia Pacific	482	27,0	10	2,1	517	28,4	9	1,7	1,20		Algorithm converged.	0,48	2,97	0,003		Algorithm converged.	-0,014	0,020	1,19		Algorithm converged.	0,49	2,91	0,6998		0,84		Algorithm converged.	0,34	2,05
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	5	2,7	184	10,1	4	2,2	1,26		Algorithm converged.	0,33	4,78	0,006		Algorithm converged.	-0,026	0,037	1,26		Algorithm converged.	0,34	4,61	0,7301		0,80		Algorithm converged.	0,22	2,92
	DEPRESSIVE SYMPTOM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISORIENTATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMOTIONAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMOTIONAL DISTRESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENURESIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITO-PELVIC PAIN/PENETRATION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HALLUCINATION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ILLUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	USA/Canada	262	14,7	82	31,3	252	13,8	78	31,0	1,02		Algorithm converged.	0,70	1,48	0,003		Algorithm converged.	-0,077	0,084		1,01		Algorithm converged.	0,78	1,31	0,9326	-	0,99		Algorithm converged.	0,76	1,28
		Western Europe	814	45,7	111	13,6	824	45,2	121	14,7	0,92		Algorithm converged.	0,69	1,21	-0,010		Algorithm converged.	-0,044	0,023		0,93		Algorithm converged.	0,73	1,18	0,5432		1,08		Algorithm converged.	0,85	1,37
		Asia Pacific	482	27,0	82	17,0	517	28,4	87	16,8	1,01		Algorithm converged.	0,73	1,41	0,002		Algorithm converged.	-0,045	0,048		1,01		Algorithm converged.	0,77	1,33	0,9380		0,99		Algorithm converged.	0,75	1,30
		Latin America	42	2,4	0	0,0	45	2,5	3	6,7	0,00		Algorithm converged.	0,00	NE	-0,088	*	WARNING: The relative Hessian convergence criterion of 3.7931764934 is greater than the limit of 0.0001. The convergence is questionable.	-0,404	0,229		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	10	5,5	184	10,1	12	6,5	0,83		Algorithm converged.	0,35	1,97	-0,011		Algorithm converged.	-0,059	0,038	0,84		Algorithm converged.	0,37	1,89	0,6702		1,19		Algorithm converged.	0,53	2,69
	IRRITABILITY	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016	0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	2	0,2	824	45,2	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,005		Algorithm converged.	-0,012	0,002	0,34		Algorithm converged.	0,07	1,67	0,1825		2,96		Algorithm converged.	0,60	14,64
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIBIDO DECREASED	USA/Canada	262	14,7	5	1,9	252	13,8	6	2,4	0,80		Algorithm converged.	0,24	2,65	-0,005		Algorithm converged.	-0,030	0,020	0,80		Algorithm converged.	0,25	2,59	0,7119	-	1,25		Algorithm converged.	0,39	4,04
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	LIBIDO DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOSS OF LIBIDO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAJOR DEPRESSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780		1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MANIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENTAL DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENTAL STATUS CHANGES	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIXED ANXIETY AND DEPRESSIVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MOOD ALTERED	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016	0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	14	1,7	824	45,2	6	0,7	2,39		Algorithm converged.	0,91	6,24	0,010		Algorithm converged.	-0,001	0,021	2,36		Algorithm converged.	0,91	6,12	0,0766		0,42		Algorithm converged.	0,16	1,10
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MOOD SWINGS	USA/Canada	262	14,7	6	2,3	252	13,8	6	2,4	0,96		Algorithm converged.	0,31	3,02	-0,001		Algorithm converged.	-0,027	0,025	0,96		Algorithm converged.	0,31	2,94	0,9456	-	1,04		Algorithm converged.	0,34	3,18
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	NERVOUSNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHTMARE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOPHAGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	ORGANIC BRAIN SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PANIC ATTACK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PARASOMNIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERSISTENT DEPRESSIVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSONALITY CHANGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POOR QUALITY SLEEP	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHIATRIC SYMPTOM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESTLESSNESS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SELF ESTEEM DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SLEEP DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	18	2,2	824	45,2	16	1,9	1,14		Algorithm converged.	0,58	2,26	0,003		Algorithm converged.	-0,011	0,017		1,14		Algorithm converged.	0,58	2,22	0,7022		0,88		Algorithm converged.	0,45	1,71
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	2	1,1	1,52		Algorithm converged.	0,25	9,18	0,006		Algorithm converged.	-0,018	0,029		1,51		Algorithm converged.	0,25	8,92	0,6505		0,66		Algorithm converged.	0,11	3,92
	STRESS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TEARFULNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THINKING ABNORMAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOMITING PSYCHOGENIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	44	16,8	252	13,8	44	17,5	0,95		Algorithm converged.	0,60	1,51	-0,007		Algorithm converged.	-0,072	0,058	0,96		Algorithm converged.	0,66	1,41	0,8411	-	1,04		Algorithm converged.	0,71	1,52
		Western Europe	814	45,7	57	7,0	824	45,2	58	7,0	0,99		Algorithm converged.	0,68	1,45	0,000		Algorithm converged.	-0,025	0,024	0,99		Algorithm converged.	0,70	1,42	0,9770		1,01		Algorithm converged.	0,71	1,43
		Asia Pacific	482	27,0	24	5,0	517	28,4	29	5,6	0,88		Algorithm converged.	0,51	1,54	-0,006		Algorithm converged.	-0,034	0,021	0,89		Algorithm converged.	0,52	1,50	0,6573		1,13		Algorithm converged.	0,67	1,91
		Latin America	42	2,4	3	7,1	45	2,5	5	11,1	0,62		Algorithm converged.	0,14	2,75	-0,040		Algorithm converged.	-0,160	0,081	0,64		Algorithm converged.	0,16	2,53	0,5268		1,56		Algorithm converged.	0,40	6,11
		Other	183	10,3	10	5,5	184	10,1	7	3,8	1,46		Algorithm converged.	0,54	3,93	0,017		Algorithm converged.	-0,026	0,060	1,44		Algorithm converged.	0,56	3,69	0,4521		0,70		Algorithm converged.	0,27	1,79
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026	1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLADDER DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLADDER PROLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COSTOVERTEBRAL ANGLE TENDERNESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS HAEMORRHAGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CYSTITIS INTERSTITIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CYSTITIS NONINFECTIVE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69	
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSURIA	USA/Canada	262	14,7	16	6,1	252	13,8	11	4,4	1,42		Algorithm converged.	0,65	3,13	0,017		Algorithm converged.	-0,021	0,056		1,40		Algorithm converged.	0,66	2,96	0,3789	-	0,71		Algorithm converged.	0,34	1,51
		Western Europe	814	45,7	25	3,1	824	45,2	29	3,5	0,87		Algorithm converged.	0,50	1,50	-0,004		Algorithm converged.	-0,022	0,013		0,87		Algorithm converged.	0,52	1,48	0,6118		1,15		Algorithm converged.	0,68	1,94
		Asia Pacific	482	27,0	6	1,2	517	28,4	7	1,4	0,92		Algorithm converged.	0,31	2,75	-0,001		Algorithm converged.	-0,015	0,013		0,92		Algorithm converged.	0,31	2,72	0,8791		1,09		Algorithm converged.	0,37	3,21
		Latin America	42	2,4	3	7,1	45	2,5	4	8,9	0,79		Algorithm converged.	0,17	3,75	-0,017		Algorithm converged.	-0,131	0,096		0,80		Algorithm converged.	0,19	3,38	0,7654		1,24		Algorithm converged.	0,30	5,23
		Other	183	10,3	3	1,6	184	10,1	4	2,2	0,75		Algorithm converged.	0,17	3,40	-0,005		Algorithm converged.	-0,033	0,023		0,75		Algorithm converged.	0,17	3,32	0,7091		1,33		Algorithm converged.	0,30	5,84
	HAEMATURIA	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016		0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009		0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTONIC BLADDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCONTINENCE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOCYTURIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICTURITION DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICTURITION URGENCY	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEPHROLITHIASIS	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028		3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	NOCTURIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POLLAKIURIA	USA/Canada	262	14,7	6	2,3	252	13,8	12	4,8	0,47		Algorithm converged.	0,17	1,27	-0,025		Algorithm converged.	-0,057	0,007	0,48		Algorithm converged.	0,18	1,26	0,1369	-	2,08		Algorithm converged.	0,79	5,46
		Western Europe	814	45,7	7	0,9	824	45,2	7	0,8	1,01		Algorithm converged.	0,35	2,90	0,000		Algorithm converged.	-0,009	0,009	1,01		Algorithm converged.	0,36	2,87	0,9817		0,99		Algorithm converged.	0,35	2,80
		Asia Pacific	482	27,0	5	1,0	517	28,4	6	1,2	0,89		Algorithm converged.	0,27	2,94	-0,001		Algorithm converged.	-0,014	0,012	0,89		Algorithm converged.	0,27	2,91	0,8522		1,12		Algorithm converged.	0,34	3,64

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POLYURIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROTEINURIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	RENAL FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	RENAL IMPAIRMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RENAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STRANGURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	STRESS URINARY INCONTINENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	URETERIC OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URETEROLITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URGE INCONTINENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY HESITATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY INCONTINENCE	USA/Canada	262	14,7	1	0,4	252	13,8	5	2,0	0,19		Algorithm converged.	0,02	1,63	-0,016		Algorithm converged.	-0,035	0,003	0,19		Algorithm converged.	0,02	1,64	0,1311	-	5,20		Algorithm converged.	0,61	44,19
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT PAIN	USA/Canada	262	14,7	8	3,1	252	13,8	2	0,8	3,94		Algorithm converged.	0,83	18,72	0,023		Algorithm converged.	-0,001	0,046	3,85		Algorithm converged.	0,82	17,94	0,0863	-	0,26		Algorithm converged.	0,06	1,21
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE ODOUR ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UROGENITAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	USA/Canada	262	14,7	69	26,3	252	13,8	68	27,0	0,97		Algorithm converged.	0,65	1,43	-0,006		Algorithm converged.	-0,083	0,070	0,98		Algorithm converged.	0,73	1,30	0,8680	-	1,02		Algorithm converged.	0,77	1,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	191	23,5	824	45,2	171	20,8	1,17		Algorithm converged.	0,93	1,48	0,027		Algorithm converged.	-0,013	0,067		1,13		Algorithm converged.	0,94	1,36	0,1864		0,88		Algorithm converged.	0,74	1,06
		Asia Pacific	482	27,0	47	9,8	517	28,4	42	8,1	1,22		Algorithm converged.	0,79	1,89	0,016		Algorithm converged.	-0,019	0,052		1,20		Algorithm converged.	0,81	1,79	0,3677		0,83		Algorithm converged.	0,56	1,24
		Latin America	42	2,4	1	2,4	45	2,5	7	15,6	0,13		Algorithm converged.	0,02	1,13	-0,132		Algorithm converged.	-0,247	-0,016		0,15		Algorithm converged.	0,02	1,19	0,0731		6,53		Algorithm converged.	0,84	50,89
		Other	183	10,3	14	7,7	184	10,1	24	13,0	0,55		Algorithm converged.	0,28	1,11	-0,054		Algorithm converged.	-0,116	0,008		0,59		Algorithm converged.	0,31	1,10	0,0951		1,70		Algorithm converged.	0,91	3,19
	AMENORRHOEA	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026		1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	25	3,1	824	45,2	26	3,2	0,97		Algorithm converged.	0,56	1,70	-0,001		Algorithm converged.	-0,018	0,016		0,97		Algorithm converged.	0,57	1,67	0,9220		1,03		Algorithm converged.	0,60	1,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATROPHIC VULVOVAGINITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BARTHOLIN'S CYST	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BREAST ATROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BREAST CALCIFICATIONS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CYST	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST DISCHARGE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREAST DISCOLOURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREAST DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007		0,32		Algorithm converged.	0,03	3,06	0,3231	-		3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006		1,01		Algorithm converged.	0,20	5,00	0,9880			0,99		Algorithm converged.	0,20	4,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST ENGORGEMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ENLARGEMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST INDURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	BREAST INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	1	0,1	5,09		Algorithm converged.	0,59	43,63	0,005		Algorithm converged.	-0,001	0,011	5,06		Algorithm converged.	0,59	43,23	0,1384		0,20		Algorithm converged.	0,02	1,69
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST MASS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	9	1,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	0,034	*	WARNING: The relative Hessian convergence criterion of 14.806859023 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,105		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	BREAST OEDEMA	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007		0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79	
		Western Europe	814	45,7	18	2,2	824	45,2	7	0,8	2,64		Algorithm converged.	1,10	6,35	0,014		Algorithm converged.	0,002	0,026		2,60		Algorithm converged.	1,09	6,20	0,0307		0,38		Algorithm converged.	0,16	0,91	
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86	
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	4	2,2	0,25		Algorithm converged.	0,03	2,23	-0,016		Algorithm converged.	-0,040	0,007		0,25		Algorithm converged.	0,03	2,23	0,2148		3,98		Algorithm converged.	0,45	35,25
	BREAST PAIN	USA/Canada	262	14,7	17	6,5	252	13,8	25	9,9	0,63		Algorithm converged.	0,33	1,20	-0,034		Algorithm converged.	-0,082	0,013		0,65		Algorithm converged.	0,36	1,18	0,1594	-	1,53		Algorithm converged.	0,85	2,76
		Western Europe	814	45,7	47	5,8	824	45,2	48	5,8	0,99		Algorithm converged.	0,65	1,50	-0,001		Algorithm converged.	-0,023	0,022		0,99		Algorithm converged.	0,67	1,46	0,9646		1,01		Algorithm converged.	0,68	1,49
		Asia Pacific	482	27,0	9	1,9	517	28,4	3	0,6	3,26		Algorithm converged.	0,88	12,11	0,013		Algorithm converged.	-0,001	0,027		3,22		Algorithm converged.	0,88	11,82	0,0782		0,31		Algorithm converged.	0,08	1,14
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	2	1,1	184	10,1	4	2,2	0,50		Algorithm converged.	0,09	2,75	-0,011		Algorithm converged.	-0,037	0,015		0,50		Algorithm converged.	0,09	2,71	0,4238		1,99		Algorithm converged.	0,37	10,73
	BREAST SWELLING	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST TENDERNESS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CERVICAL POLYP	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	DYSMENORRHOEA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPAREUNIA	USA/Canada	262	14,7	10	3,8	252	13,8	4	1,6	2,46		Algorithm converged.	0,76	7,95	0,022		Algorithm converged.	-0,006	0,050	2,40		Algorithm converged.	0,76	7,57	0,1337	-	0,42		Algorithm converged.	0,13	1,31
		Western Europe	814	45,7	4	0,5	824	45,2	9	1,1	0,45		Algorithm converged.	0,14	1,46	-0,006		Algorithm converged.	-0,015	0,003	0,45		Algorithm converged.	0,14	1,46	0,1823		2,22		Algorithm converged.	0,69	7,19
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ECTROPION OF CERVIX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENDOMETRIAL HYPERPLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ENDOMETRIAL HYPERTROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ENDOMETRIAL THICKENING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENDOMETRIOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERECTILE DYSFUNCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GALACTORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL PROLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL RASH	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL TRACT INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAVY MENSTRUAL BLEEDING	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTERMENSTRUAL BLEEDING	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	6	0,7	824	45,2	7	0,8	0,87		Algorithm converged.	0,29	2,59	-0,001		Algorithm converged.	-0,010	0,007	0,87		Algorithm converged.	0,29	2,57	0,7978		1,15		Algorithm converged.	0,39	3,41
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk							
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENOMETRORRHAGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENOPAUSAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENOPAUSAL SYMPTOMS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	4	2,2	0,25		Algorithm converged.	0,03	2,23	-0,016		Algorithm converged.	-0,040	0,007	0,25		Algorithm converged.	0,03	2,23	0,2148		3,98		Algorithm converged.	0,45	35,25
	MENSTRUATION IRREGULAR	USA/Canada	262	14,7	6	2,3	252	13,8	7	2,8	0,82		Algorithm converged.	0,27	2,48	-0,005		Algorithm converged.	-0,032	0,022	0,82		Algorithm converged.	0,28	2,42	0,7252	-	1,21		Algorithm converged.	0,41	3,56
		Western Europe	814	45,7	16	2,0	824	45,2	22	2,7	0,73		Algorithm converged.	0,38	1,40	-0,007		Algorithm converged.	-0,022	0,008	0,74		Algorithm converged.	0,39	1,39	0,3458		1,36		Algorithm converged.	0,72	2,57
		Asia Pacific	482	27,0	6	1,2	517	28,4	7	1,4	0,92		Algorithm converged.	0,31	2,75	-0,001		Algorithm converged.	-0,015	0,013	0,92		Algorithm converged.	0,31	2,72	0,8791		1,09		Algorithm converged.	0,37	3,21
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	NIPPLE EXUDATE BLOODY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OLIGOMENORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	OVARIAN CYST	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902			0,99		Algorithm converged.	0,14	7,00						
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PELVIC CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC FLOOR MUSCLE WEAKNESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PELVIC PAIN	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013		0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002		0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	5	1,0	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERINEAL ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERINEAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERINEAL ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PREMATURE MENOPAUSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURITUS GENITAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	REPRODUCTIVE TRACT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETRACTED NIPPLE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UTERINE POLYP	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL DISCHARGE	USA/Canada	262	14,7	6	2,3	252	13,8	4	1,6	1,45		Algorithm converged.	0,41	5,21	0,007		Algorithm converged.	-0,017	0,031	1,44		Algorithm converged.	0,41	5,05	0,5665	-	0,69		Algorithm converged.	0,20	2,43
		Western Europe	814	45,7	16	2,0	824	45,2	8	1,0	2,05		Algorithm converged.	0,87	4,81	0,010		Algorithm converged.	-0,002	0,022	2,02		Algorithm converged.	0,87	4,70	0,1011		0,49		Algorithm converged.	0,21	1,15
		Asia Pacific	482	27,0	7	1,5	517	28,4	5	1,0	1,51		Algorithm converged.	0,48	4,79	0,005		Algorithm converged.	-0,009	0,018	1,50		Algorithm converged.	0,48	4,70	0,4849		0,67		Algorithm converged.	0,21	2,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731458976 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VAGINAL HAEMORRHAGE	USA/Canada	262	14,7	3	1,1	252	13,8	7	2,8	0,41		Algorithm converged.	0,10	1,59	-0,016		Algorithm converged.	-0,040	0,008		0,41		Algorithm converged.	0,11	1,58	0,1954	-	2,43		Algorithm converged.	0,63	9,28
		Western Europe	814	45,7	6	0,7	824	45,2	6	0,7	1,01		Algorithm converged.	0,33	3,15	0,000		Algorithm converged.	-0,008	0,008		1,01		Algorithm converged.	0,33	3,13	0,9831		0,99		Algorithm converged.	0,32	3,05
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014		2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VAGINAL LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VULVAL ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	VULVAR EROSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL BURNING SENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DRYNESS	USA/Canada	262	14,7	14	5,3	252	13,8	21	8,3	0,62		Algorithm converged.	0,31	1,25	-0,030		Algorithm converged.	-0,074	0,014		0,64		Algorithm converged.	0,33	1,23	0,1828	-	1,56		Algorithm converged.	0,81	3,00
		Western Europe	814	45,7	42	5,2	824	45,2	38	4,6	1,13		Algorithm converged.	0,72	1,76	0,005		Algorithm converged.	-0,015	0,026		1,12		Algorithm converged.	0,73	1,72	0,6071		0,89		Algorithm converged.	0,58	1,37
		Asia Pacific	482	27,0	7	1,5	517	28,4	4	0,8	1,89		Algorithm converged.	0,55	6,50	0,007		Algorithm converged.	-0,006	0,020		1,88		Algorithm converged.	0,55	6,37	0,3126		0,53		Algorithm converged.	0,16	1,81
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL ERYTHEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL INFLAMMATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL PRURITUS	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	182	69,5	252	13,8	174	69,0	1,02		Algorithm converged.	0,70	1,48	0,004		Algorithm converged.	-0,076	0,084	1,01		Algorithm converged.	0,90	1,13	0,9182	0,6403	0,99		Algorithm converged.	0,89	1,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	407	50,0	824	45,2	372	45,1	1,22		Algorithm converged.	1,00	1,48	0,049		Algorithm converged.	0,000	0,097	1,11		Algorithm converged.	1,00	1,23	0,0495		0,90		Algorithm converged.	0,82	1,00
		Asia Pacific	482	27,0	187	38,8	517	28,4	185	35,8	1,14		Algorithm converged.	0,88	1,47	0,030		Algorithm converged.	-0,030	0,090	1,08		Algorithm converged.	0,92	1,27	0,3249		0,92		Algorithm converged.	0,79	1,08
		Latin America	42	2,4	10	23,8	45	2,5	8	17,8	1,45		Algorithm converged.	0,51	4,10	0,060		Algorithm converged.	-0,110	0,231	1,34		Algorithm converged.	0,58	3,07	0,4898		0,75		Algorithm converged.	0,33	1,71
		Other	183	10,3	63	34,4	184	10,1	52	28,3	1,33		Algorithm converged.	0,86	2,07	0,062		Algorithm converged.	-0,033	0,156	1,22		Algorithm converged.	0,90	1,65	0,2046		0,82		Algorithm converged.	0,61	1,11
	ACUTE RESPIRATORY DISTRESS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLERGIC SINUSITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APNOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	2	1,1	1,52		Algorithm converged.	0,25	9,18	0,006		Algorithm converged.	-0,018	0,029	1,51		Algorithm converged.	0,25	8,92	0,6505		0,66		Algorithm converged.	0,11	3,92
	ASTHMA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	3	0,6	517	28,4	5	1,0	0,64		Algorithm converged.	0,15	2,70	-0,003		Algorithm converged.	-0,014	0,008	0,64		Algorithm converged.	0,15	2,68	0,5447		1,55		Algorithm converged.	0,37	6,47
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ATELECTASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BRONCHIAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIECTASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOPNEUMOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731458976 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRONCHOSTENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	CATARRH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE
		Western Europe	814	45,7	9	1,1	824	45,2	7	0,8	1,30		Algorithm converged.	0,48	3,52	0,003		Algorithm converged.	-0,007	0,012		1,30		Algorithm converged.	0,49	3,48	0,5993			0,77		Algorithm converged.	0,29	2,05						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
	CHOKING SENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	COUGH	USA/Canada	262	14,7	75	28,6	252	13,8	62	24,6	1,23		Algorithm converged.	0,83	1,82	0,040		Algorithm converged.	-0,036	0,117		1,16		Algorithm converged.	0,87	1,55	0,3037	-		0,86		Algorithm converged.	0,64	1,15	
		Western Europe	814	45,7	110	13,5	824	45,2	128	15,5	0,85		Algorithm converged.	0,65	1,12	-0,020		Algorithm converged.	-0,054	0,014		0,87		Algorithm converged.	0,69	1,10	0,2466			1,15		Algorithm converged.	0,91	1,46	
		Asia Pacific	482	27,0	80	16,6	517	28,4	71	13,7	1,25		Algorithm converged.	0,88	1,77	0,029		Algorithm converged.	-0,016	0,073		1,21		Algorithm converged.	0,90	1,62	0,2074			0,83		Algorithm converged.	0,62	1,11	
		Latin America	42	2,4	4	9,5	45	2,5	3	6,7	1,47		Algorithm converged.	0,31	7,01	0,029		Algorithm converged.	-0,086	0,143		1,43		Algorithm converged.	0,34	6,01	0,6265			0,70		Algorithm converged.	0,17	2,94	
		Other	183	10,3	16	8,7	184	10,1	19	10,3	0,83		Algorithm converged.	0,41	1,67	-0,016		Algorithm converged.	-0,076	0,044		0,85		Algorithm converged.	0,45	1,59	0,6063			1,18		Algorithm converged.	0,63	2,22	
	DRY THROAT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSAESTHESIA PHARYNX	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPHONIA	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	16	2,0	824	45,2	8	1,0	2,05		Algorithm converged.	0,87	4,81	0,010		Algorithm converged.	-0,002	0,022		2,02		Algorithm converged.	0,87	4,70	0,1011		0,49		Algorithm converged.	0,21	1,15
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011		1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018		0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	DYSPNOEA	USA/Canada	262	14,7	64	24,4	252	13,8	63	25,0	0,97		Algorithm converged.	0,65	1,45	-0,006		Algorithm converged.	-0,080	0,069		0,98		Algorithm converged.	0,72	1,32	0,8804	-	1,02		Algorithm converged.	0,76	1,38
		Western Europe	814	45,7	104	12,8	824	45,2	106	12,9	0,99		Algorithm converged.	0,74	1,33	-0,001		Algorithm converged.	-0,033	0,032		0,99		Algorithm converged.	0,77	1,28	0,9577		1,01		Algorithm converged.	0,78	1,30
		Asia Pacific	482	27,0	14	2,9	517	28,4	29	5,6	0,50		Algorithm converged.	0,26	0,96	-0,027		Algorithm converged.	-0,052	-0,002		0,52		Algorithm converged.	0,28	0,97	0,0392		1,93		Algorithm converged.	1,03	3,61
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	11	6,0	184	10,1	5	2,7	2,29		Algorithm converged.	0,78	6,73	0,033		Algorithm converged.	-0,009	0,075		2,21		Algorithm converged.	0,78	6,24	0,1335		0,45		Algorithm converged.	0,16	1,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPNOEA EXERTIONAL	USA/Canada	262	14,7	9	3,4	252	13,8	16	6,3	0,52		Algorithm converged.	0,23	1,21	-0,029		Algorithm converged.	-0,066	0,008	0,54		Algorithm converged.	0,24	1,20	0,1314	-	1,85		Algorithm converged.	0,83	4,11
		Western Europe	814	45,7	10	1,2	824	45,2	14	1,7	0,72		Algorithm converged.	0,32	1,63	-0,005		Algorithm converged.	-0,016	0,007	0,72		Algorithm converged.	0,32	1,62	0,4302		1,38		Algorithm converged.	0,62	3,10
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	EPISTAXIS	USA/Canada	262	14,7	58	22,1	252	13,8	49	19,4	1,18		Algorithm converged.	0,77	1,81	0,027		Algorithm converged.	-0,043	0,097	1,14		Algorithm converged.	0,81	1,60	0,4529	-	0,88		Algorithm converged.	0,63	1,23
		Western Europe	814	45,7	180	22,1	824	45,2	132	16,0	1,49		Algorithm converged.	1,16	1,91	0,061		Algorithm converged.	0,023	0,099	1,38		Algorithm converged.	1,13	1,69	0,0018		0,72		Algorithm converged.	0,59	0,89
		Asia Pacific	482	27,0	39	8,1	517	28,4	36	7,0	1,18		Algorithm converged.	0,73	1,88	0,011		Algorithm converged.	-0,021	0,044	1,16		Algorithm converged.	0,75	1,80	0,4994		0,86		Algorithm converged.	0,56	1,33
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	25	13,7	184	10,1	19	10,3	1,37		Algorithm converged.	0,73	2,59	0,033		Algorithm converged.	-0,033	0,100	1,32		Algorithm converged.	0,76	2,32	0,3276		0,76		Algorithm converged.	0,43	1,32
	HAEMOPTYSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HICCUPS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	4	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERVENTILATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPOXIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	INTERSTITIAL LUNG DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LARYNGEAL HAEMORRHAGE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL INFLAMMATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	5	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9998		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LARYNGEAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER RESPIRATORY TRACT CONGESTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG INFILTRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL CONGESTION	USA/Canada	262	14,7	23	8,8	252	13,8	34	13,5	0,62		Algorithm converged.	0,35	1,08	-0,047		Algorithm converged.	-0,101	0,007	0,65		Algorithm converged.	0,39	1,07	0,0921	-	1,54		Algorithm converged.	0,93	2,53
		Western Europe	814	45,7	4	0,5	824	45,2	8	1,0	0,50		Algorithm converged.	0,15	1,68	-0,005		Algorithm converged.	-0,013	0,003	0,51		Algorithm converged.	0,15	1,67	0,2646		1,98		Algorithm converged.	0,60	6,54
		Asia Pacific	482	27,0	6	1,2	517	28,4	2	0,4	3,25		Algorithm converged.	0,65	16,16	0,009		Algorithm converged.	-0,003	0,020	3,22		Algorithm converged.	0,65	15,87	0,1511		0,31		Algorithm converged.	0,06	1,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	3	6,7	0,00		Algorithm converged.	0,00	NE	-0,088	*	WARNING: The relative Hessian convergence criterion of 3.7931764934 is greater than the limit of 0.0001. The convergence is questionable.	-0,404	0,229		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	3	1,6	184	10,1	1	0,5	3,05		Algorithm converged.	0,31	29,60	0,011		Algorithm converged.	-0,010	0,032		3,02		Algorithm converged.	0,32	28,73	0,3370		0,33		Algorithm converged.	0,03	3,16
	NASAL CRUSTING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	6	0,7	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	10	1,2	824	45,2	4	0,5	2,55		Algorithm converged.	0,80	8,16	0,007		Algorithm converged.	-0,002	0,016	2,53		Algorithm converged.	0,80	8,04	0,1153		0,40		Algorithm converged.	0,12	1,25
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASAL DRYNESS	USA/Canada	262	14,7	12	4,6	252	13,8	8	3,2	1,46		Algorithm converged.	0,59	3,64	0,014		Algorithm converged.	-0,019	0,047	1,44		Algorithm converged.	0,60	3,47	0,4131	-	0,69		Algorithm converged.	0,29	1,67
		Western Europe	814	45,7	22	2,7	824	45,2	11	1,3	2,05		Algorithm converged.	0,99	4,26	0,014		Algorithm converged.	0,000	0,027	2,02		Algorithm converged.	0,99	4,15	0,0539		0,49		Algorithm converged.	0,24	1,01
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	4	2,2	184	10,1	7	3,8	0,57		Algorithm converged.	0,16	1,96	-0,016		Algorithm converged.	-0,051	0,019		0,57		Algorithm converged.	0,17	1,93	0,3699		1,74		Algorithm converged.	0,52	5,84
	NASAL INFLAMMATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	13	1,6	824	45,2	8	1,0	1,66		Algorithm converged.	0,68	4,02	0,006		Algorithm converged.	-0,005	0,017		1,64		Algorithm converged.	0,69	3,95	0,2651		0,61		Algorithm converged.	0,25	1,46
		Asia Pacific	482	27,0	1	0,2	517	28,4	5	1,0	0,21		Algorithm converged.	0,02	1,83	-0,008		Algorithm converged.	-0,017	0,002		0,21		Algorithm converged.	0,03	1,83	0,1593		4,66		Algorithm converged.	0,55	39,76
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL MUCOSAL DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL POLYPS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL SEPTUM ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL TURBINATE HYPERTROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL ULCER	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OROPHARYNGEAL DISCOMFORT	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009		0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGEAL PAIN	USA/Canada	262	14,7	50	19,1	252	13,8	31	12,3	1,68		Algorithm converged.	1,03	2,73	0,068		Algorithm converged.	0,005	0,130		1,55		Algorithm converged.	1,03	2,35	0,0373	-	0,64		Algorithm converged.	0,43	0,97
		Western Europe	814	45,7	61	7,5	824	45,2	54	6,6	1,16		Algorithm converged.	0,79	1,69	0,009		Algorithm converged.	-0,015	0,034		1,14		Algorithm converged.	0,80	1,63	0,4568		0,87		Algorithm converged.	0,61	1,24
		Asia Pacific	482	27,0	46	9,5	517	28,4	47	9,1	1,06		Algorithm converged.	0,69	1,62	0,005		Algorithm converged.	-0,032	0,041		1,05		Algorithm converged.	0,71	1,55	0,8057		0,95		Algorithm converged.	0,65	1,40

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	11	6,0	184	10,1	2	1,1	5,82		Algorithm converged.	1,27	26,64	0,049		Algorithm converged.	0,012	0,087	5,53		Algorithm converged.	1,24	24,60	0,0247		0,18		Algorithm converged.	0,04	0,80
	OROPHARYNGEAL PLAQUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOPNOEA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAINFUL RESPIRATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PARANASAL SINUS DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	5	2,0	0,19		Algorithm converged.	0,02	1,63	-0,016		Algorithm converged.	-0,035	0,003		0,19		Algorithm converged.	0,02	1,64	0,1311	-	5,20		Algorithm converged.	0,61	44,19
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PARANASAL SINUS HYPERSECRETION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHARYNGEAL ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHARYNGEAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PHARYNGEAL SWELLING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PLEURAL EFFUSION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	PLEURAL THICKENING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	PLEURITIC PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PNEUMOTHORAX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PRODUCTIVE COUGH	USA/Canada	262	14,7	7	2,7	252	13,8	4	1,6	1,70		Algorithm converged.	0,49	5,89	0,011		Algorithm converged.	-0,014	0,036	1,68		Algorithm converged.	0,50	5,68	0,4014	-	0,59		Algorithm converged.	0,18	2,00
		Western Europe	814	45,7	7	0,9	824	45,2	7	0,8	1,01		Algorithm converged.	0,35	2,90	0,000		Algorithm converged.	-0,009	0,009	1,01		Algorithm converged.	0,36	2,87	0,9817		0,99		Algorithm converged.	0,35	2,80
		Asia Pacific	482	27,0	5	1,0	517	28,4	6	1,2	0,89		Algorithm converged.	0,27	2,94	-0,001		Algorithm converged.	-0,014	0,012	0,89		Algorithm converged.	0,27	2,91	0,8522		1,12		Algorithm converged.	0,34	3,64
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY CONGESTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	PULMONARY HYPERTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PULMONARY OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RALES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REFLUX LARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT CONGESTION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT IRRITATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHINALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHINITIS ALLERGIC	USA/Canada	262	14,7	6	2,3	252	13,8	10	4,0	0,57		Algorithm converged.	0,20	1,58	-0,017		Algorithm converged.	-0,047	0,013	0,58		Algorithm converged.	0,21	1,56	0,2799	-	1,73		Algorithm converged.	0,64	4,70
		Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
		Asia Pacific	482	27,0	12	2,5	517	28,4	12	2,3	1,07		Algorithm converged.	0,48	2,42	0,002		Algorithm converged.	-0,017	0,021	1,07		Algorithm converged.	0,49	2,36	0,8620		0,93		Algorithm converged.	0,42	2,06
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	RHINORRHOEA	USA/Canada	262	14,7	31	11,8	252	13,8	19	7,5	1,65		Algorithm converged.	0,90	3,00	0,043		Algorithm converged.	-0,008	0,094	1,57		Algorithm converged.	0,91	2,70	0,1046	-	0,64		Algorithm converged.	0,37	1,10
		Western Europe	814	45,7	65	8,0	824	45,2	48	5,8	1,40		Algorithm converged.	0,95	2,06	0,022		Algorithm converged.	-0,003	0,046	1,37		Algorithm converged.	0,96	1,97	0,0861		0,73		Algorithm converged.	0,51	1,05
		Asia Pacific	482	27,0	34	7,1	517	28,4	17	3,3	2,23		Algorithm converged.	1,23	4,05	0,038		Algorithm converged.	0,010	0,065	2,15		Algorithm converged.	1,21	3,79	0,0085		0,47		Algorithm converged.	0,26	0,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Other	183	10,3	12	6,6	184	10,1	8	4,3	1,54		Algorithm converged.	0,62	3,87	0,022		Algorithm converged.	-0,024	0,069	1,51		Algorithm converged.	0,63	3,60	0,3551		0,66		Algorithm converged.	0,28	1,58						
	SINUS CONGESTION	USA/Canada	262	14,7	6	2,3	252	13,8	4	1,6	1,45		Algorithm converged.	0,41	5,21	0,007		Algorithm converged.	-0,017	0,031	1,44		Algorithm converged.	0,41	5,05	0,5665	-	0,69		Algorithm converged.	0,20	2,43						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	SINUS DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53						
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SLEEP APNOEA SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SNEEZING	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028	1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPUTUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRIDOR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYPNOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROAT IRRITATION	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002169 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROAT TIGHTNESS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRACHEAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT CONGESTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT IRRITATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER-AIRWAY COUGH SYNDROME	USA/Canada	262	14,7	15	5,7	252	13,8	13	5,2	1,12		Algorithm converged.	0,52	2,40	0,006		Algorithm converged.	-0,034	0,045	1,11		Algorithm converged.	0,54	2,29	0,7774	-	0,90		Algorithm converged.	0,44	1,86
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOCAL CORD INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHEEZING	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	236	90,1	252	13,8	224	88,9	1,13		Algorithm converged.	0,65	1,99	0,012		Algorithm converged.	-0,041	0,065	1,01		Algorithm converged.	0,95	1,08	0,6611	0,7784	0,99		Algorithm converged.	0,93	1,05
		Western Europe	814	45,7	718	88,2	824	45,2	702	85,2	1,30		Algorithm converged.	0,98	1,73	0,030		Algorithm converged.	-0,003	0,063	1,04		Algorithm converged.	1,00	1,08	0,0728		0,97		Algorithm converged.	0,93	1,00
		Asia Pacific	482	27,0	421	87,3	517	28,4	428	82,8	1,44		Algorithm converged.	1,01	2,04	0,046		Algorithm converged.	0,002	0,090	1,06		Algorithm converged.	1,00	1,11	0,0432		0,95		Algorithm converged.	0,90	1,00
		Latin America	42	2,4	28	66,7	45	2,5	26	57,8	1,46		Algorithm converged.	0,61	3,50	0,089		Algorithm converged.	-0,114	0,292	1,15		Algorithm converged.	0,83	1,60	0,3937		0,87		Algorithm converged.	0,62	1,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	163	89,1	184	10,1	154	83,7	1,59		Algorithm converged.	0,87	2,91	0,054		Algorithm converged.	-0,016	0,124		1,06		Algorithm converged.	0,98	1,15	0,1344		0,94		Algorithm converged.	0,87	1,02
	ACNE	USA/Canada	262	14,7	6	2,3	252	13,8	5	2,0	1,16		Algorithm converged.	0,35	3,84	0,003		Algorithm converged.	-0,022	0,028		1,15		Algorithm converged.	0,36	3,73	0,8108	-	0,87		Algorithm converged.	0,27	2,80
		Western Europe	814	45,7	12	1,5	824	45,2	14	1,7	0,87		Algorithm converged.	0,40	1,88	-0,002		Algorithm converged.	-0,014	0,010		0,87		Algorithm converged.	0,40	1,86	0,7161		1,15		Algorithm converged.	0,54	2,48
		Asia Pacific	482	27,0	5	1,0	517	28,4	2	0,4	2,70		Algorithm converged.	0,52	13,98	0,007		Algorithm converged.	-0,004	0,017		2,68		Algorithm converged.	0,52	13,76	0,2371		0,37		Algorithm converged.	0,07	1,91
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ACTINIC KERATOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA	USA/Canada	262	14,7	172	65,6	252	13,8	168	66,7	0,96		Algorithm converged.	0,66	1,38	-0,010		Algorithm converged.	-0,092	0,072	0,98		Algorithm converged.	0,87	1,11	0,8074	0,9552	1,02		Algorithm converged.	0,90	1,15
		Western Europe	814	45,7	512	62,9	824	45,2	519	63,0	1,00		Algorithm converged.	0,82	1,22	-0,001		Algorithm converged.	-0,048	0,046	1,00		Algorithm converged.	0,93	1,08	0,9712		1,00		Algorithm converged.	0,93	1,08
		Asia Pacific	482	27,0	370	76,8	517	28,4	386	74,7	1,12		Algorithm converged.	0,84	1,50	0,021		Algorithm converged.	-0,032	0,074	1,03		Algorithm converged.	0,96	1,10	0,4385		0,97		Algorithm converged.	0,91	1,04
		Latin America	42	2,4	19	45,2	45	2,5	22	48,9	0,86		Algorithm converged.	0,37	2,01	-0,037		Algorithm converged.	-0,246	0,173	0,93		Algorithm converged.	0,59	1,45	0,7337		1,08		Algorithm converged.	0,69	1,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	133	72,7	184	10,1	134	72,8	0,99		Algorithm converged.	0,63	1,57	-0,001		Algorithm converged.	-0,093	0,090	1,00		Algorithm converged.	0,88	1,13	0,9745		1,00		Algorithm converged.	0,88	1,14
	ALOPECIA AREATA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA TOTALIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ANGIOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLISTER	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BLISTER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUTTERFLY RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLD SWEAT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMAL CYST	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS	USA/Canada	262	14,7	2	0,8	252	13,8	11	4,4	0,17		Algorithm converged.	0,04	0,77	-0,036		Algorithm converged.	-0,063	-0,009	0,17		Algorithm converged.	0,04	0,78	0,0224	-	5,72		Algorithm converged.	1,28	25,54
		Western Europe	814	45,7	52	6,4	824	45,2	34	4,1	1,59		Algorithm converged.	1,02	2,47	0,023		Algorithm converged.	0,001	0,044	1,55		Algorithm converged.	1,02	2,36	0,0420		0,65		Algorithm converged.	0,42	0,98
		Asia Pacific	482	27,0	23	4,8	517	28,4	24	4,6	1,03		Algorithm converged.	0,57	1,85	0,001		Algorithm converged.	-0,025	0,028	1,03		Algorithm converged.	0,59	1,80	0,9230		0,97		Algorithm converged.	0,56	1,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034	1,34		Algorithm converged.	0,30	5,91	0,6984		0,75		Algorithm converged.	0,17	3,29
	DERMATITIS ACNEIFORM	USA/Canada	262	14,7	21	8,0	252	13,8	14	5,6	1,48		Algorithm converged.	0,74	2,98	0,025		Algorithm converged.	-0,019	0,068	1,44		Algorithm converged.	0,75	2,77	0,2718	-	0,69		Algorithm converged.	0,36	1,33
		Western Europe	814	45,7	24	2,9	824	45,2	9	1,1	2,75		Algorithm converged.	1,27	5,96	0,019		Algorithm converged.	0,005	0,032	2,70		Algorithm converged.	1,26	5,77	0,0104		0,37		Algorithm converged.	0,17	0,79
		Asia Pacific	482	27,0	17	3,5	517	28,4	10	1,9	1,85		Algorithm converged.	0,84	4,09	0,016		Algorithm converged.	-0,004	0,036	1,82		Algorithm converged.	0,84	3,94	0,1268		0,55		Algorithm converged.	0,25	1,19
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS ALLERGIC	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002085 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATITIS ATOPIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DERMATITIS BULLOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005		0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DERMATITIS CONTACT	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	6	1,2	517	28,4	5	1,0	1,29		Algorithm converged.	0,39	4,26	0,003		Algorithm converged.	-0,010	0,016		1,29		Algorithm converged.	0,40	4,19	0,6751		0,78		Algorithm converged.	0,24	2,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS DIAPER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG ERUPTION	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	2	0,4	1,61		Algorithm converged.	0,27	9,69	0,002		Algorithm converged.	-0,006	0,011	1,61		Algorithm converged.	0,27	9,59	0,6015		0,62		Algorithm converged.	0,10	3,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	USA/Canada	262	14,7	51	19,5	252	13,8	48	19,0	1,03		Algorithm converged.	0,66	1,59	0,004		Algorithm converged.	-0,064	0,072	1,02		Algorithm converged.	0,72	1,46	0,9044	-	0,98		Algorithm converged.	0,69	1,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	119	14,6	824	45,2	95	11,5	1,31		Algorithm converged.	0,98	1,75	0,031		Algorithm converged.	-0,002	0,064	1,27		Algorithm converged.	0,99	1,63	0,0644		0,79		Algorithm converged.	0,61	1,01
		Asia Pacific	482	27,0	41	8,5	517	28,4	41	7,9	1,08		Algorithm converged.	0,69	1,70	0,006		Algorithm converged.	-0,028	0,040	1,07		Algorithm converged.	0,71	1,62	0,7404		0,93		Algorithm converged.	0,62	1,41
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	15	8,2	184	10,1	5	2,7	3,20		Algorithm converged.	1,14	8,99	0,055		Algorithm converged.	0,009	0,101	3,02		Algorithm converged.	1,12	8,13	0,0290		0,33		Algorithm converged.	0,12	0,89
	DYSHIDROTIC ECZEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECCHYMOSIS	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ECZEMA	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	13	1,6	824	45,2	9	1,1	1,47		Algorithm converged.	0,62	3,46	0,005		Algorithm converged.	-0,006	0,016	1,46		Algorithm converged.	0,63	3,40	0,3778		0,68		Algorithm converged.	0,29	1,59
		Asia Pacific	482	27,0	15	3,1	517	28,4	9	1,7	1,81		Algorithm converged.	0,79	4,18	0,014		Algorithm converged.	-0,005	0,033	1,79		Algorithm converged.	0,79	4,05	0,1634		0,56		Algorithm converged.	0,25	1,27
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ECZEMA ASTEATOTIC	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPIDERMOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	USA/Canada	262	14,7	39	14,9	252	13,8	28	11,1	1,40		Algorithm converged.	0,83	2,35	0,038		Algorithm converged.	-0,020	0,096	1,34		Algorithm converged.	0,85	2,11	0,2064	-	0,75		Algorithm converged.	0,47	1,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	116	14,3	824	45,2	105	12,7	1,14		Algorithm converged.	0,86	1,51	0,015		Algorithm converged.	-0,018	0,048		1,12		Algorithm converged.	0,87	1,43	0,3721		0,89		Algorithm converged.	0,70	1,14
		Asia Pacific	482	27,0	16	3,3	517	28,4	19	3,7	0,90		Algorithm converged.	0,46	1,77	-0,004		Algorithm converged.	-0,026	0,019		0,90		Algorithm converged.	0,47	1,74	0,7602		1,11		Algorithm converged.	0,58	2,13
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055		0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	17	9,3	184	10,1	16	8,7	1,08		Algorithm converged.	0,53	2,20	0,006		Algorithm converged.	-0,053	0,064		1,07		Algorithm converged.	0,56	2,05	0,8424		0,94		Algorithm converged.	0,49	1,80
	ERYTHEMA MULTIFORME	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA NODOSUM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXCESSIVE GRANULATION TISSUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXFOLIATIVE RASH	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAIR GROWTH ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAND DERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HANGNAIL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HIRSUTISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERHIDROSIS	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026	1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	6	0,7	824	45,2	9	1,1	0,67		Algorithm converged.	0,24	1,90	-0,004		Algorithm converged.	-0,013	0,006	0,67		Algorithm converged.	0,24	1,89	0,4536		1,48		Algorithm converged.	0,53	4,14
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	HYPERKERATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTRICHOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006		1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009		0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTERTRIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ITCHING SCAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LICHEN PLANUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LIVEDO RETICULARIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MACULE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MADAROSIS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MECHANICAL URTICARIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MILIARIA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	5	1,0	517	28,4	1	0,2	5,41		Algorithm converged.	0,63	46,46	0,008		Algorithm converged.	-0,001	0,018	5,36		Algorithm converged.	0,63	45,74	0,1246		0,19		Algorithm converged.	0,02	1,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED BLEEDING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED DISORDER	USA/Canada	262	14,7	5	1,9	252	13,8	2	0,8	2,43		Algorithm converged.	0,47	12,65	0,011		Algorithm converged.	-0,009	0,031	2,40		Algorithm converged.	0,47	12,28	0,2916	-	0,42		Algorithm converged.	0,08	2,12
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED TENDERNESS	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005	0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE		
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
	NAIL DISCOLOURATION	USA/Canada	262	14,7	38	14,5	252	13,8	33	13,1	1,13		Algorithm converged.	0,68	1,86	0,014		Algorithm converged.	-0,046	0,074		1,11		Algorithm converged.	0,72	1,71	0,6439	-	0,90		Algorithm converged.	0,59	1,39		
		Western Europe	814	45,7	23	2,8	824	45,2	16	1,9	1,47		Algorithm converged.	0,77	2,80	0,009		Algorithm converged.	-0,006	0,024		1,46		Algorithm converged.	0,77	2,73	0,2437		0,69		Algorithm converged.	0,37	1,29		
		Asia Pacific	482	27,0	68	14,1	517	28,4	81	15,7	0,88		Algorithm converged.	0,62	1,25	-0,016		Algorithm converged.	-0,060	0,029		0,90		Algorithm converged.	0,67	1,21	0,4898		1,11		Algorithm converged.	0,82	1,50		
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055		0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84		
		Other	183	10,3	6	3,3	184	10,1	9	4,9	0,66		Algorithm converged.	0,23	1,89	-0,016		Algorithm converged.	-0,057	0,024		0,67		Algorithm converged.	0,24	1,85	0,4387		1,49		Algorithm converged.	0,54	4,11		
	NAIL DISCOMFORT	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	USA/Canada	262	14,7	42	16,0	252	13,8	35	13,9	1,18		Algorithm converged.	0,73	1,92	0,021		Algorithm converged.	-0,040	0,083	1,15		Algorithm converged.	0,76	1,75	0,4971	-	0,87		Algorithm converged.	0,57	1,31
		Western Europe	814	45,7	118	14,5	824	45,2	110	13,3	1,10		Algorithm converged.	0,83	1,46	0,011		Algorithm converged.	-0,022	0,045	1,09		Algorithm converged.	0,85	1,38	0,5028		0,92		Algorithm converged.	0,72	1,17
		Asia Pacific	482	27,0	53	11,0	517	28,4	52	10,1	1,10		Algorithm converged.	0,74	1,66	0,009		Algorithm converged.	-0,029	0,047	1,09		Algorithm converged.	0,76	1,57	0,6292		0,91		Algorithm converged.	0,64	1,31
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	8	4,4	184	10,1	7	3,8	1,16		Algorithm converged.	0,41	3,26	0,006		Algorithm converged.	-0,035	0,046	1,15		Algorithm converged.	0,43	3,10	0,7840		0,87		Algorithm converged.	0,32	2,35
	NAIL DYSTROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	12	1,5	824	45,2	12	1,5	1,01		Algorithm converged.	0,45	2,27	0,000		Algorithm converged.	-0,011	0,012	1,01		Algorithm converged.	0,46	2,24	0,9760		0,99		Algorithm converged.	0,45	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	NAIL GROWTH ABNORMAL	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL PIGMENTATION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL RIDGING	USA/Canada	262	14,7	8	3,1	252	13,8	9	3,6	0,85		Algorithm converged.	0,32	2,24	-0,005		Algorithm converged.	-0,036	0,026	0,85		Algorithm converged.	0,34	2,18	0,7430	-	1,17		Algorithm converged.	0,46	2,98
		Western Europe	814	45,7	19	2,3	824	45,2	12	1,5	1,62		Algorithm converged.	0,78	3,35	0,009		Algorithm converged.	-0,004	0,022	1,60		Algorithm converged.	0,78	3,28	0,1967		0,62		Algorithm converged.	0,30	1,28
		Asia Pacific	482	27,0	11	2,3	517	28,4	13	2,5	0,91		Algorithm converged.	0,40	2,04	-0,002		Algorithm converged.	-0,021	0,017	0,91		Algorithm converged.	0,41	2,01	0,8107		1,10		Algorithm converged.	0,50	2,44
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	1	0,5	3,05		Algorithm converged.	0,31	29,60	0,011		Algorithm converged.	-0,010	0,032	3,02		Algorithm converged.	0,32	28,73	0,3370		0,33		Algorithm converged.	0,03	3,16
	NAIL TOXICITY	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	47	5,8	824	45,2	34	4,1	1,42		Algorithm converged.	0,91	2,24	0,016		Algorithm converged.	-0,005	0,037	1,40		Algorithm converged.	0,91	2,15	0,1261		0,71		Algorithm converged.	0,46	1,10
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	1	0,5	4,09		Algorithm converged.	0,45	36,94	0,016		Algorithm converged.	-0,007	0,040	4,02		Algorithm converged.	0,45	35,64	0,2112		0,25		Algorithm converged.	0,03	2,20
	NEURODERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NIGHT SWEATS	USA/Canada	262	14,7	8	3,1	252	13,8	13	5,2	0,58		Algorithm converged.	0,24	1,42	-0,021		Algorithm converged.	-0,055	0,013	0,59		Algorithm converged.	0,25	1,40	0,2340	-	1,69		Algorithm converged.	0,71	4,01
		Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010	1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NODULAR RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ONYCHALGIA	USA/Canada	262	14,7	4	1,5	252	13,8	5	2,0	0,77		Algorithm converged.	0,20	2,89	-0,005		Algorithm converged.	-0,027	0,018	0,77		Algorithm converged.	0,21	2,83	0,6935	-	1,30		Algorithm converged.	0,35	4,78
		Western Europe	814	45,7	9	1,1	824	45,2	7	0,8	1,30		Algorithm converged.	0,48	3,52	0,003		Algorithm converged.	-0,007	0,012	1,30		Algorithm converged.	0,49	3,48	0,5993		0,77		Algorithm converged.	0,29	2,05

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOCLASIS	USA/Canada	262	14,7	7	2,7	252	13,8	4	1,6	1,70		Algorithm converged.	0,49	5,89	0,011		Algorithm converged.	-0,014	0,036	1,68		Algorithm converged.	0,50	5,68	0,4014	-	0,59		Algorithm converged.	0,18	2,00
		Western Europe	814	45,7	11	1,4	824	45,2	16	1,9	0,69		Algorithm converged.	0,32	1,50	-0,006		Algorithm converged.	-0,018	0,006	0,70		Algorithm converged.	0,32	1,49	0,3509		1,44		Algorithm converged.	0,67	3,08
		Asia Pacific	482	27,0	6	1,2	517	28,4	4	0,8	1,62		Algorithm converged.	0,45	5,76	0,005		Algorithm converged.	-0,008	0,017	1,61		Algorithm converged.	0,46	5,67	0,4591		0,62		Algorithm converged.	0,18	2,19
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOLYSIS	USA/Canada	262	14,7	1	0,4	252	13,8	9	3,6	0,10		Algorithm converged.	0,01	0,82	-0,032		Algorithm converged.	-0,056	-0,008		0,11		Algorithm converged.	0,01	0,84	0,0333	-	9,36		Algorithm converged.	1,19	73,32
		Western Europe	814	45,7	49	6,0	824	45,2	59	7,2	0,83		Algorithm converged.	0,56	1,23	-0,011		Algorithm converged.	-0,035	0,013		0,84		Algorithm converged.	0,58	1,21	0,3531		1,19		Algorithm converged.	0,82	1,72
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007		0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOMADESIS	USA/Canada	262	14,7	27	10,3	252	13,8	20	7,9	1,33		Algorithm converged.	0,73	2,44	0,024		Algorithm converged.	-0,026	0,073		1,30		Algorithm converged.	0,75	2,25	0,3535	-	0,77		Algorithm converged.	0,44	1,34
		Western Europe	814	45,7	24	2,9	824	45,2	30	3,6	0,80		Algorithm converged.	0,47	1,39	-0,007		Algorithm converged.	-0,024	0,010		0,81		Algorithm converged.	0,48	1,37	0,4336		1,23		Algorithm converged.	0,73	2,09
		Asia Pacific	482	27,0	23	4,8	517	28,4	19	3,7	1,31		Algorithm converged.	0,71	2,44	0,011		Algorithm converged.	-0,014	0,036		1,30		Algorithm converged.	0,72	2,35	0,3895		0,77		Algorithm converged.	0,42	1,40
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	5	2,7	184	10,1	4	2,2	1,26		Algorithm converged.	0,33	4,78	0,006		Algorithm converged.	-0,026	0,037		1,26		Algorithm converged.	0,34	4,61	0,7301		0,80		Algorithm converged.	0,22	2,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOMALACIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN OF SKIN	USA/Canada	262	14,7	8	3,1	252	13,8	7	2,8	1,10		Algorithm converged.	0,39	3,09	0,003		Algorithm converged.	-0,026	0,032	1,10		Algorithm converged.	0,40	2,99	0,8528	-	0,91		Algorithm converged.	0,33	2,47
		Western Europe	814	45,7	10	1,2	824	45,2	2	0,2	5,11		Algorithm converged.	1,12	23,40	0,010		Algorithm converged.	0,002	0,018	5,06		Algorithm converged.	1,11	23,03	0,0359		0,20		Algorithm converged.	0,04	0,90
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	USA/Canada	262	14,7	19	7,3	252	13,8	10	4,0	1,89		Algorithm converged.	0,86	4,15	0,033		Algorithm converged.	-0,007	0,072	1,83		Algorithm converged.	0,87	3,85	0,1131	-	0,55		Algorithm converged.	0,26	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	89	10,9	824	45,2	57	6,9	1,65		Algorithm converged.	1,17	2,34	0,040		Algorithm converged.	0,013	0,068	1,58		Algorithm converged.	1,15	2,17	0,0048		0,63		Algorithm converged.	0,46	0,87
		Asia Pacific	482	27,0	40	8,3	517	28,4	43	8,3	1,00		Algorithm converged.	0,64	1,56	0,000		Algorithm converged.	-0,034	0,034	1,00		Algorithm converged.	0,66	1,51	0,9916		1,00		Algorithm converged.	0,66	1,51
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	9	4,9	184	10,1	2	1,1	4,71		Algorithm converged.	1,00	22,09	0,038		Algorithm converged.	0,004	0,073	4,52		Algorithm converged.	0,99	20,66	0,0514		0,22		Algorithm converged.	0,05	1,01
	PAPULE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PEAU D'ORANGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PETECHIAE	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHOTOSENSITIVITY REACTION	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PIGMENTATION DISORDER	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	4	0,8	517	28,4	9	1,7	0,47		Algorithm converged.	0,14	1,54	-0,009		Algorithm converged.	-0,023	0,005	0,48		Algorithm converged.	0,15	1,54	0,2151		2,10		Algorithm converged.	0,65	6,77
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PITYRIASIS ROSEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLANTAR ERYTHEMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURIGO	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	USA/Canada	262	14,7	55	21,0	252	13,8	24	9,5	2,52		Algorithm converged.	1,51	4,22	0,115		Algorithm converged.	0,053	0,176	2,20		Algorithm converged.	1,41	3,45	0,0005	-	0,45		Algorithm converged.	0,29	0,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	116	14,3	824	45,2	61	7,4	2,08		Algorithm converged.	1,50	2,88	0,068		Algorithm converged.	0,039	0,098	1,93		Algorithm converged.	1,43	2,58	<.0001		0,52		Algorithm converged.	0,39	0,70
		Asia Pacific	482	27,0	76	15,8	517	28,4	67	13,0	1,26		Algorithm converged.	0,88	1,79	0,028		Algorithm converged.	-0,015	0,072	1,22		Algorithm converged.	0,90	1,65	0,2062		0,82		Algorithm converged.	0,61	1,11
		Latin America	42	2,4	1	2,4	45	2,5	5	11,1	0,20		Algorithm converged.	0,02	1,74	-0,087		Algorithm converged.	-0,190	0,015	0,21		Algorithm converged.	0,03	1,76	0,1516		4,67		Algorithm converged.	0,57	38,32
		Other	183	10,3	13	7,1	184	10,1	6	3,3	2,27		Algorithm converged.	0,84	6,10	0,038		Algorithm converged.	-0,007	0,084	2,18		Algorithm converged.	0,85	5,61	0,1065		0,46		Algorithm converged.	0,18	1,18
	PSORIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PURPURA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH	USA/Canada	262	14,7	90	34,4	252	13,8	59	23,4	1,71		Algorithm converged.	1,16	2,52	0,109		Algorithm converged.	0,032	0,187	1,47		Algorithm converged.	1,11	1,94	0,0071	-	0,68		Algorithm converged.	0,52	0,90
		Western Europe	814	45,7	194	23,8	824	45,2	158	19,2	1,32		Algorithm converged.	1,04	1,67	0,047		Algorithm converged.	0,007	0,086	1,24		Algorithm converged.	1,03	1,50	0,0222		0,80		Algorithm converged.	0,67	0,97
		Asia Pacific	482	27,0	145	30,1	517	28,4	125	24,2	1,35		Algorithm converged.	1,02	1,79	0,059		Algorithm converged.	0,004	0,114	1,24		Algorithm converged.	1,01	1,53	0,0362		0,80		Algorithm converged.	0,66	0,99
		Latin America	42	2,4	2	4,8	45	2,5	4	8,9	0,51		Algorithm converged.	0,09	2,96	-0,041		Algorithm converged.	-0,146	0,064	0,54		Algorithm converged.	0,10	2,77	0,4569		1,87		Algorithm converged.	0,36	9,67
		Other	183	10,3	30	16,4	184	10,1	22	12,0	1,44		Algorithm converged.	0,80	2,61	0,044		Algorithm converged.	-0,027	0,116	1,37		Algorithm converged.	0,82	2,28	0,2258		0,73		Algorithm converged.	0,44	1,22
	RASH ERYTHEMATOUS	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	RASH FOLLICULAR	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	RASH MACULAR	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033		1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31	
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008		2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004		0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RASH MACULO-PAPULAR	USA/Canada	262	14,7	20	7,6	252	13,8	20	7,9	0,96		Algorithm converged.	0,50	1,83	-0,003		Algorithm converged.	-0,049	0,043		0,96		Algorithm converged.	0,53	1,74	0,8980	-	1,04		Algorithm converged.	0,57	1,89
		Western Europe	814	45,7	22	2,7	824	45,2	11	1,3	2,05		Algorithm converged.	0,99	4,26	0,014		Algorithm converged.	0,000	0,027		2,02		Algorithm converged.	0,99	4,15	0,0539		0,49		Algorithm converged.	0,24	1,01
		Asia Pacific	482	27,0	15	3,1	517	28,4	9	1,7	1,81		Algorithm converged.	0,79	4,18	0,014		Algorithm converged.	-0,005	0,033		1,79		Algorithm converged.	0,79	4,05	0,1634		0,56		Algorithm converged.	0,25	1,27
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	3	1,6	184	10,1	3	1,6	1,01		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,026	0,026		1,01		Algorithm converged.	0,21	4,92	0,9946		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH PAPULAR	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH PRURITIC	USA/Canada	262	14,7	3	1,1	252	13,8	4	1,6	0,72		Algorithm converged.	0,16	3,24	-0,004		Algorithm converged.	-0,025	0,016	0,72		Algorithm converged.	0,16	3,19	0,6668	-	1,39		Algorithm converged.	0,31	6,13
		Western Europe	814	45,7	6	0,7	824	45,2	7	0,8	0,87		Algorithm converged.	0,29	2,59	-0,001		Algorithm converged.	-0,010	0,007	0,87		Algorithm converged.	0,29	2,57	0,7978		1,15		Algorithm converged.	0,39	3,41
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH VESICULAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ROSACEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SCAB	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SCAR PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	10	1,2	824	45,2	9	1,1	1,13		Algorithm converged.	0,46	2,79	0,001		Algorithm converged.	-0,009	0,012	1,12		Algorithm converged.	0,46	2,75	0,7969		0,89		Algorithm converged.	0,36	2,18
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEBORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEBORRHOEIC DERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SENSITIVE SKIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ATROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SKIN BURNING SENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN DEPIGMENTATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN DISCOLOURATION	USA/Canada	262	14,7	8	3,1	252	13,8	6	2,4	1,29		Algorithm converged.	0,44	3,78	0,007		Algorithm converged.	-0,021	0,035	1,28		Algorithm converged.	0,45	3,64	0,6406	-	0,78		Algorithm converged.	0,27	2,22
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN DISORDER	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028	1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
		Western Europe	814	45,7	6	0,7	824	45,2	6	0,7	1,01		Algorithm converged.	0,33	3,15	0,000		Algorithm converged.	-0,008	0,008	1,01		Algorithm converged.	0,33	3,13	0,9831		0,99		Algorithm converged.	0,32	3,05
		Asia Pacific	482	27,0	3	0,6	517	28,4	3	0,6	1,07		Algorithm converged.	0,22	5,34	0,000		Algorithm converged.	-0,009	0,010	1,07		Algorithm converged.	0,22	5,29	0,9314		0,93		Algorithm converged.	0,19	4,60
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN EROSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	USA/Canada	262	14,7	9	3,4	252	13,8	11	4,4	0,78		Algorithm converged.	0,32	1,91	-0,009		Algorithm converged.	-0,043	0,024	0,79		Algorithm converged.	0,33	1,87	0,5867	-	1,27		Algorithm converged.	0,54	3,01
		Western Europe	814	45,7	9	1,1	824	45,2	8	1,0	1,14		Algorithm converged.	0,44	2,97	0,001		Algorithm converged.	-0,008	0,011	1,14		Algorithm converged.	0,44	2,94	0,7880		0,88		Algorithm converged.	0,34	2,26
		Asia Pacific	482	27,0	8	1,7	517	28,4	6	1,2	1,44		Algorithm converged.	0,50	4,17	0,005		Algorithm converged.	-0,010	0,020	1,43		Algorithm converged.	0,50	4,09	0,5047		0,70		Algorithm converged.	0,24	2,00
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034	1,34		Algorithm converged.	0,30	5,91	0,6984		0,75		Algorithm converged.	0,17	3,29
	SKIN FISSURES	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	21	2,6	824	45,2	19	2,3	1,12		Algorithm converged.	0,60	2,10	0,003		Algorithm converged.	-0,012	0,018	1,12		Algorithm converged.	0,61	2,07	0,7196		0,89		Algorithm converged.	0,48	1,65
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	SKIN HYPERPIGMENTATION	USA/Canada	262	14,7	10	3,8	252	13,8	15	6,0	0,63		Algorithm converged.	0,28	1,42	-0,021		Algorithm converged.	-0,059	0,016	0,64		Algorithm converged.	0,29	1,40	0,2649	-	1,56		Algorithm converged.	0,71	3,41
		Western Europe	814	45,7	17	2,1	824	45,2	7	0,8	2,49		Algorithm converged.	1,03	6,04	0,012		Algorithm converged.	0,001	0,024	2,46		Algorithm converged.	1,02	5,90	0,0439		0,41		Algorithm converged.	0,17	0,98
		Asia Pacific	482	27,0	46	9,5	517	28,4	44	8,5	1,13		Algorithm converged.	0,74	1,75	0,010		Algorithm converged.	-0,025	0,046	1,12		Algorithm converged.	0,76	1,66	0,5690		0,89		Algorithm converged.	0,60	1,32
		Latin America	42	2,4	4	9,5	45	2,5	1	2,2	4,63		Algorithm converged.	0,50	43,24	0,073		Algorithm converged.	-0,026	0,172	4,29		Algorithm converged.	0,50	36,81	0,1847		0,23		Algorithm converged.	0,03	2,00
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	SKIN HYPERTROPHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	SKIN HYPOPIGMENTATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	SKIN INDURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	SKIN IRRITATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	10	1,2	824	45,2	8	1,0	1,27		Algorithm converged.	0,50	3,23	0,003		Algorithm converged.	-0,008	0,013	1,27		Algorithm converged.	0,50	3,19	0,6179		0,79		Algorithm converged.	0,31	1,99
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN MASS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SKIN ODOUR ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN PLAQUE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN SWELLING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TIGHTNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	16	2,0	824	45,2	8	1,0	2,05		Algorithm converged.	0,87	4,81	0,010		Algorithm converged.	-0,002	0,022	2,02		Algorithm converged.	0,87	4,70	0,1011		0,49		Algorithm converged.	0,21	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103		2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN ULCER	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028		3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	6	0,7	824	45,2	4	0,5	1,52		Algorithm converged.	0,43	5,41	0,003		Algorithm converged.	-0,005	0,010		1,52		Algorithm converged.	0,43	5,36	0,5164		0,66		Algorithm converged.	0,19	2,33
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014		2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	SKIN WRINKLING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPIDER NAEVUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TELANGIECTASIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TOXIC EPIDERMAL NECROLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE		-	NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TOXIC SKIN ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	UMBILICAL ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URTICARIA	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	10	1,2	824	45,2	9	1,1	1,13		Algorithm converged.	0,46	2,79	0,001		Algorithm converged.	-0,009	0,012	1,12		Algorithm converged.	0,46	2,75	0,7969		0,89		Algorithm converged.	0,36	2,18
		Asia Pacific	482	27,0	15	3,1	517	28,4	16	3,1	1,01		Algorithm converged.	0,49	2,06	0,000		Algorithm converged.	-0,021	0,022	1,01		Algorithm converged.	0,50	2,01	0,9875		0,99		Algorithm converged.	0,50	1,99
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URTICARIA CONTACT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URTICARIA PAPULAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	XERODERMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
SOCIAL CIRCUMSTANCE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	INADEQUATE DIET	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENOPAUSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
SURGICAL AND MEDICAL PROCEDURE	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	3	0,4	824	45,2	7	0,8	0,43		Algorithm converged.	0,11	1,68	-0,005		Algorithm converged.	-0,012	0,003	0,43		Algorithm converged.	0,11	1,67	0,2250		2,31		Algorithm converged.	0,60	8,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASTRINGENT THERAPY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,004		Algorithm converged.	-0,010	0,003	0,40		Algorithm converged.	0,08	2,08	0,2790		2,47		Algorithm converged.	0,48	12,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST RECONSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	BREAST TUMOUR EXCISION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CENTRAL VENOUS CATHETER REMOVAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CENTRAL VENOUS CATHETERISATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DENTAL CARE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOSPITALISATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS OPERATION	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028	3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH RESTORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	148	56,5	252	13,8	143	56,7	0,99		Algorithm converged.	0,70	1,40	-0,003		Algorithm converged.	-0,088	0,083	1,00		Algorithm converged.	0,86	1,16	0,9530	0,1794	1,00		Algorithm converged.	0,86	1,17
		Western Europe	814	45,7	344	42,3	824	45,2	349	42,4	1,00		Algorithm converged.	0,82	1,21	-0,001		Algorithm converged.	-0,049	0,047	1,00		Algorithm converged.	0,89	1,12	0,9693		1,00		Algorithm converged.	0,90	1,12
		Asia Pacific	482	27,0	97	20,1	517	28,4	121	23,4	0,82		Algorithm converged.	0,61	1,11	-0,033		Algorithm converged.	-0,084	0,018	0,86		Algorithm converged.	0,68	1,09	0,2109		1,16		Algorithm converged.	0,92	1,47
		Latin America	42	2,4	4	9,5	45	2,5	8	17,8	0,49		Algorithm converged.	0,13	1,76	-0,083		Algorithm converged.	-0,225	0,060	0,54		Algorithm converged.	0,17	1,65	0,2765		1,87		Algorithm converged.	0,61	5,74
		Other	183	10,3	37	20,2	184	10,1	55	29,9	0,59		Algorithm converged.	0,37	0,96	-0,097		Algorithm converged.	-0,185	-0,009	0,68		Algorithm converged.	0,47	0,97	0,0348		1,48		Algorithm converged.	1,03	2,13
	ANGIOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOSCLEROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AORTIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ARTERIOSCLEROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE FLUCTUATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOODY DISCHARGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CIRCULATORY COLLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023		1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006		1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DRY GANGRENE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020		1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	9	1,1	824	45,2	2	0,2	4,60		Algorithm converged.	0,99	21,33	0,009		Algorithm converged.	0,001	0,017		4,56		Algorithm converged.	0,99	21,02	0,0520		0,22		Algorithm converged.	0,05	1,01
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EMBOLISM VENOUS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUSHING	USA/Canada	262	14,7	12	4,6	252	13,8	14	5,6	0,82		Algorithm converged.	0,37	1,80	-0,010		Algorithm converged.	-0,048	0,028	0,82		Algorithm converged.	0,39	1,75	0,6145	-	1,21		Algorithm converged.	0,57	2,57
		Western Europe	814	45,7	36	4,4	824	45,2	29	3,5	1,27		Algorithm converged.	0,77	2,09	0,009		Algorithm converged.	-0,010	0,028	1,26		Algorithm converged.	0,78	2,03	0,3503		0,80		Algorithm converged.	0,49	1,29
		Asia Pacific	482	27,0	8	1,7	517	28,4	10	1,9	0,86		Algorithm converged.	0,33	2,19	-0,003		Algorithm converged.	-0,019	0,014	0,86		Algorithm converged.	0,34	2,16	0,7448		1,17		Algorithm converged.	0,46	2,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731458976 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	3	1,6	184	10,1	4	2,2	0,75		Algorithm converged.	0,17	3,40	-0,005		Algorithm converged.	-0,033	0,023	0,75		Algorithm converged.	0,17	3,32	0,7091		1,33		Algorithm converged.	0,30	5,84
	HAEMATOMA	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	4	0,5	824	45,2	4	0,5	1,01		Algorithm converged.	0,25	4,06	0,000		Algorithm converged.	-0,007	0,007	1,01		Algorithm converged.	0,25	4,03	0,9862		0,99		Algorithm converged.	0,25	3,94
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHAGE	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	USA/Canada	262	14,7	97	37,0	252	13,8	98	38,9	0,92		Algorithm converged.	0,65	1,32	-0,019		Algorithm converged.	-0,103	0,065	0,95		Algorithm converged.	0,76	1,19	0,6630	-	1,05		Algorithm converged.	0,84	1,31
		Western Europe	814	45,7	184	22,6	824	45,2	186	22,6	1,00		Algorithm converged.	0,79	1,26	0,000		Algorithm converged.	-0,040	0,041	1,00		Algorithm converged.	0,84	1,20	0,9878		1,00		Algorithm converged.	0,83	1,19
		Asia Pacific	482	27,0	34	7,1	517	28,4	43	8,3	0,84		Algorithm converged.	0,52	1,34	-0,013		Algorithm converged.	-0,046	0,020	0,85		Algorithm converged.	0,55	1,31	0,4552		1,18		Algorithm converged.	0,77	1,82
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	18	9,8	184	10,1	26	14,1	0,66		Algorithm converged.	0,35	1,26	-0,043		Algorithm converged.	-0,109	0,023	0,70		Algorithm converged.	0,40	1,22	0,2089		1,44		Algorithm converged.	0,82	2,53
	HYPERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	HYPERTENSION	USA/Canada	262	14,7	15	5,7	252	13,8	14	5,6	1,03		Algorithm converged.	0,49	2,19	0,002		Algorithm converged.	-0,038	0,042	1,03		Algorithm converged.	0,51	2,09	0,9336	-	0,97		Algorithm converged.	0,48	1,97
		Western Europe	814	45,7	41	5,0	824	45,2	50	6,1	0,82		Algorithm converged.	0,54	1,26	-0,010		Algorithm converged.	-0,032	0,012	0,83		Algorithm converged.	0,56	1,24	0,3632		1,20		Algorithm converged.	0,81	1,80
		Asia Pacific	482	27,0	9	1,9	517	28,4	19	3,7	0,50		Algorithm converged.	0,22	1,11	-0,018		Algorithm converged.	-0,038	0,002	0,51		Algorithm converged.	0,23	1,11	0,0902		1,97		Algorithm converged.	0,90	4,31
		Latin America	42	2,4	2	4,8	45	2,5	3	6,7	0,70		Algorithm converged.	0,11	4,41	-0,019		Algorithm converged.	-0,116	0,078	0,71		Algorithm converged.	0,13	4,07	0,7045		1,40		Algorithm converged.	0,25	7,97
		Other	183	10,3	7	3,8	184	10,1	11	6,0	0,63		Algorithm converged.	0,24	1,65	-0,022		Algorithm converged.	-0,066	0,023	0,64		Algorithm converged.	0,25	1,61	0,3442		1,56		Algorithm converged.	0,62	3,94
	HYPERTENSIVE CRISIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOTENSION	USA/Canada	262	14,7	9	3,4	252	13,8	5	2,0	1,76		Algorithm converged.	0,58	5,32	0,015		Algorithm converged.	-0,013	0,042	1,73		Algorithm converged.	0,59	5,10	0,3190	-	0,58		Algorithm converged.	0,20	1,70
		Western Europe	814	45,7	24	2,9	824	45,2	17	2,1	1,44		Algorithm converged.	0,77	2,71	0,009		Algorithm converged.	-0,006	0,024	1,43		Algorithm converged.	0,77	2,64	0,2542		0,70		Algorithm converged.	0,38	1,29
		Asia Pacific	482	27,0	4	0,8	517	28,4	5	1,0	0,86		Algorithm converged.	0,23	3,21	-0,001		Algorithm converged.	-0,013	0,010	0,86		Algorithm converged.	0,23	3,18	0,8187		1,17		Algorithm converged.	0,31	4,31
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	3	1,6	184	10,1	3	1,6	1,01		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,026	0,026	1,01		Algorithm converged.	0,21	4,92	0,9946		0,99		Algorithm converged.	0,20	4,86
	INFERIOR VENA CAVA DILATATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERNAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JUGULAR VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,005		Algorithm converged.	-0,011	0,001	0,20		Algorithm converged.	0,02	1,73	0,1444		4,94		Algorithm converged.	0,58	42,19
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	USA/Canada	262	14,7	40	15,3	252	13,8	45	17,9	0,83		Algorithm converged.	0,52	1,32	-0,026		Algorithm converged.	-0,090	0,038	0,85		Algorithm converged.	0,58	1,26	0,4301	-	1,17		Algorithm converged.	0,79	1,73
		Western Europe	814	45,7	67	8,2	824	45,2	79	9,6	0,85		Algorithm converged.	0,60	1,19	-0,014		Algorithm converged.	-0,041	0,014	0,86		Algorithm converged.	0,63	1,17	0,3360		1,16		Algorithm converged.	0,85	1,59
		Asia Pacific	482	27,0	10	2,1	517	28,4	25	4,8	0,42		Algorithm converged.	0,20	0,88	-0,028		Algorithm converged.	-0,050	-0,005	0,43		Algorithm converged.	0,21	0,88	0,0218		2,33		Algorithm converged.	1,13	4,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731458976 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Other	183	10,3	7	3,8	184	10,1	4	2,2	1,79		Algorithm converged.	0,51	6,22	0,017		Algorithm converged.	-0,018	0,051		1,76		Algorithm converged.	0,52	5,91	0,3606			0,57		Algorithm converged.	0,17	1,91
	LYMPHORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LYMPHOSTASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORTHOSTATIC HYPOTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALLOR	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	PERIPHERAL COLDNESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL VASCULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL VENOUS DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008		1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013		0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	13	1,6	824	45,2	12	1,5	1,10		Algorithm converged.	0,50	2,42	0,001		Algorithm converged.	-0,010	0,013		1,10		Algorithm converged.	0,50	2,39	0,8164		0,91		Algorithm converged.	0,42	1,99
		Asia Pacific	482	27,0	11	2,3	517	28,4	15	2,9	0,78		Algorithm converged.	0,36	1,72	-0,006		Algorithm converged.	-0,026	0,013		0,79		Algorithm converged.	0,36	1,70	0,5402		1,27		Algorithm converged.	0,59	2,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103	2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	3	1,6	184	10,1	5	2,7	0,60		Algorithm converged.	0,14	2,53	-0,011		Algorithm converged.	-0,041	0,019	0,60		Algorithm converged.	0,15	2,49	0,4844		1,66		Algorithm converged.	0,40	6,83
	PHLEBITIS SUPERFICIAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	PREHYPERTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	SUBCLAVIAN VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009		4,05		Algorithm converged.	0,45	36,15	0,2105			0,25		Algorithm converged.	0,03	2,20						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	SUPERFICIAL VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUPERIOR VENA CAVA OCCLUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUPERIOR VENA CAVA SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOPHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSED VARICOSE VEIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	5	0,6	824	45,2	12	1,5	0,42		Algorithm converged.	0,15	1,19	-0,008		Algorithm converged.	-0,018	0,001	0,42		Algorithm converged.	0,15	1,19	0,1034		2,37		Algorithm converged.	0,84	6,70
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VARICOSE VEIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	8	1,7	517	28,4	5	1,0	1,73		Algorithm converged.	0,56	5,32	0,007		Algorithm converged.	-0,007	0,021	1,72		Algorithm converged.	0,57	5,21	0,3404		0,58		Algorithm converged.	0,19	1,77
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	VASCULAR RUPTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	16	3,3	517	28,4	14	2,7	1,23		Algorithm converged.	0,60	2,56	0,006		Algorithm converged.	-0,015	0,027	1,23		Algorithm converged.	0,60	2,48	0,5721		0,82		Algorithm converged.	0,40	1,65
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	VASODILATATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VEIN DISCOLOURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENOUS THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENOUS THROMBOSIS LIMB	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_ANYAE_S1.xls
05MAY2022 13:13

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	30	58,8	42	2,3	17	40,5	2,10		Algorithm converged.	0,92	4,82	0,183		Algorithm converged.	-0,017	0,384		1,45		Algorithm converged.	0,94	2,24	0,0904	0,5072	0,69		Algorithm converged.	0,45	1,06
		0 positive nodes, tumor > 1 cm	259	14,5	138	53,3	271	14,9	128	47,2	1,27		Algorithm converged.	0,91	1,79	0,060		Algorithm converged.	-0,025	0,145		1,13		Algorithm converged.	0,95	1,34	0,1643		0,89		Algorithm converged.	0,75	1,05
		1-3 positive nodes	891	50,0	467	52,4	905	49,7	438	48,4	1,17		Algorithm converged.	0,98	1,41	0,040		Algorithm converged.	-0,006	0,086		1,08		Algorithm converged.	0,99	1,19	0,0891		0,92		Algorithm converged.	0,84	1,01
		>= 4 positive nodes	582	32,6	307	52,7	604	33,2	302	50,0	1,12		Algorithm converged.	0,89	1,40	0,027		Algorithm converged.	-0,029	0,084		1,05		Algorithm converged.	0,94	1,18	0,3437		0,95		Algorithm converged.	0,85	1,06
	AGRANULOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	18	35,3	42	2,3	7	16,7	2,73		Algorithm converged.	1,01	7,37	0,186		Algorithm converged.	0,013	0,359	2,12		Algorithm converged.	0,98	4,58	0,0567	0,3002	0,47		Algorithm converged.	0,22	1,02
		0 positive nodes, tumor > 1 cm	259	14,5	81	31,3	271	14,9	63	23,2	1,50		Algorithm converged.	1,02	2,21	0,080		Algorithm converged.	0,005	0,156	1,35		Algorithm converged.	1,01	1,78	0,0391		0,74		Algorithm converged.	0,56	0,99
		1-3 positive nodes	891	50,0	231	25,9	905	49,7	209	23,1	1,17		Algorithm converged.	0,94	1,45	0,028		Algorithm converged.	-0,011	0,068	1,12		Algorithm converged.	0,95	1,32	0,1633		0,89		Algorithm converged.	0,76	1,05
		>= 4 positive nodes	582	32,6	174	29,9	604	33,2	154	25,5	1,25		Algorithm converged.	0,97	1,61	0,044		Algorithm converged.	-0,007	0,095	1,17		Algorithm converged.	0,97	1,41	0,0909		0,85		Algorithm converged.	0,71	1,03
	ANAEMIA MACROCYTIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BLOOD DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BONE MARROW FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DISSEMINATED INTRAVASCULAR COAGULATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EOSINOPHILIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYTHROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	9	17,6	42	2,3	6	14,3	1,29		Algorithm converged.	0,42	3,96	0,034		Algorithm converged.	-0,115	0,182	1,24		Algorithm converged.	0,48	3,19	0,6625	0,8825	0,81		Algorithm converged.	0,31	2,09
		0 positive nodes, tumor > 1 cm	259	14,5	29	11,2	271	14,9	22	8,1	1,43		Algorithm converged.	0,80	2,55	0,031		Algorithm converged.	-0,020	0,081	1,38		Algorithm converged.	0,81	2,34	0,2320		0,73		Algorithm converged.	0,43	1,23
		1-3 positive nodes	891	50,0	109	12,2	905	49,7	100	11,0	1,12		Algorithm converged.	0,84	1,50	0,012		Algorithm converged.	-0,018	0,042	1,11		Algorithm converged.	0,86	1,43	0,4344		0,90		Algorithm converged.	0,70	1,17
		>= 4 positive nodes	582	32,6	65	11,2	604	33,2	62	10,3	1,10		Algorithm converged.	0,76	1,59	0,009		Algorithm converged.	-0,026	0,044	1,09		Algorithm converged.	0,78	1,51	0,6151		0,92		Algorithm converged.	0,66	1,28
	GRANULOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	8	0,9	1,02		Algorithm converged.	0,38	2,72	0,000		Algorithm converged.	-0,009	0,009	1,02		Algorithm converged.	0,38	2,69	0,9750		0,98		Algorithm converged.	0,37	2,61
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	8	1,3	0,39		Algorithm converged.	0,10	1,46	-0,008		Algorithm converged.	-0,019	0,003	0,39		Algorithm converged.	0,10	1,46	0,1618		2,57		Algorithm converged.	0,69	9,64
	HAEMATOTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERLEUKOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCREASED TENDENCY TO BRUISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010		5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	LEUKOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	3	0,3	2,04		Algorithm converged.	0,51	8,18	0,003		Algorithm converged.	-0,003	0,010		2,03		Algorithm converged.	0,51	8,10	0,3151		0,49		Algorithm converged.	0,12	1,96
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009		1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	2	4,8	2,67		Algorithm converged.	0,51	13,97	0,070		Algorithm converged.	-0,039	0,179		2,47		Algorithm converged.	0,53	11,61	0,2519	-	0,40		Algorithm converged.	0,09	1,90
		0 positive nodes, tumor > 1 cm	259	14,5	21	8,1	271	14,9	20	7,4	1,11		Algorithm converged.	0,59	2,09	0,007		Algorithm converged.	-0,038	0,053		1,10		Algorithm converged.	0,61	1,98	0,7539		0,91		Algorithm converged.	0,51	1,64
		1-3 positive nodes	891	50,0	82	9,2	905	49,7	94	10,4	0,87		Algorithm converged.	0,64	1,19	-0,012		Algorithm converged.	-0,039	0,016		0,89		Algorithm converged.	0,67	1,17	0,3993		1,13		Algorithm converged.	0,85	1,50
		>= 4 positive nodes	582	32,6	58	10,0	604	33,2	73	12,1	0,81		Algorithm converged.	0,56	1,16	-0,021		Algorithm converged.	-0,057	0,014		0,82		Algorithm converged.	0,60	1,14	0,2453		1,21		Algorithm converged.	0,88	1,68
	LYMPH NODE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	LYMPHADENITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHADENOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006		1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LYMPHOID TISSUE HYPERPLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	MICROCYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MICROCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	7	0,8	0,72		Algorithm converged.	0,23	2,29	-0,002		Algorithm converged.	-0,010	0,005	0,73		Algorithm converged.	0,23	2,28	0,5825		1,38		Algorithm converged.	0,44	4,33
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	6	1,0	0,34		Algorithm converged.	0,07	1,71	-0,006		Algorithm converged.	-0,016	0,003	0,35		Algorithm converged.	0,07	1,71	0,1924		2,89		Algorithm converged.	0,59	14,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	18	35,3	42	2,3	6	14,3	3,27		Algorithm converged.	1,16	9,24	0,210		Algorithm converged.	0,042	0,379		2,47		Algorithm converged.	1,08	5,66	0,0324	0,1275	0,40		Algorithm converged.	0,18	0,93	
		0 positive nodes, tumor > 1 cm	259	14,5	64	24,7	271	14,9	52	19,2	1,38		Algorithm converged.	0,91	2,09	0,055		Algorithm converged.	-0,015	0,126		1,29		Algorithm converged.	0,93	1,78	0,1259		0,78		Algorithm converged.	0,56	1,07	
		1-3 positive nodes	891	50,0	239	26,8	905	49,7	232	25,6	1,06		Algorithm converged.	0,86	1,31	0,012		Algorithm converged.	-0,029	0,053		1,05		Algorithm converged.	0,90	1,22	0,5670		0,96		Algorithm converged.	0,82	1,12	
		>= 4 positive nodes	582	32,6	147	25,3	604	33,2	141	23,3	1,11		Algorithm converged.	0,85	1,45	0,019		Algorithm converged.	-0,030	0,068		1,08		Algorithm converged.	0,88	1,32	0,4425		0,92		Algorithm converged.	0,76	1,13	
	NEUTROPHILIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	NORMOCHROMIC NORMOCYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114		2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	9	3,3	1,79		Algorithm converged.	0,77	4,16	0,025		Algorithm converged.	-0,011	0,060		1,74		Algorithm converged.	0,78	3,91	0,1777		0,57		Algorithm converged.	0,26	1,29
		1-3 positive nodes	891	50,0	34	3,8	905	49,7	32	3,5	1,08		Algorithm converged.	0,66	1,77	0,003		Algorithm converged.	-0,015	0,020		1,08		Algorithm converged.	0,67	1,73	0,7525		0,93		Algorithm converged.	0,58	1,49
		>= 4 positive nodes	582	32,6	23	4,0	604	33,2	25	4,1	0,95		Algorithm converged.	0,53	1,70	-0,002		Algorithm converged.	-0,024	0,021		0,95		Algorithm converged.	0,55	1,66	0,8701		1,05		Algorithm converged.	0,60	1,82
	THROMBOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	5	11,9	0,99		Algorithm converged.	0,28	3,49	-0,001		Algorithm converged.	-0,133	0,131	0,99		Algorithm converged.	0,32	3,01	0,9834	0,1654	1,01		Algorithm converged.	0,33	3,08
		0 positive nodes, tumor > 1 cm	259	14,5	29	11,2	271	14,9	27	10,0	1,14		Algorithm converged.	0,65	1,98	0,012		Algorithm converged.	-0,040	0,065	1,12		Algorithm converged.	0,68	1,84	0,6444		0,89		Algorithm converged.	0,54	1,46
		1-3 positive nodes	891	50,0	94	10,5	905	49,7	108	11,9	0,87		Algorithm converged.	0,65	1,17	-0,014		Algorithm converged.	-0,043	0,015	0,88		Algorithm converged.	0,68	1,15	0,3538		1,13		Algorithm converged.	0,87	1,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	79	13,6	604	33,2	58	9,6	1,48		Algorithm converged.	1,03	2,12	0,040		Algorithm converged.	0,003	0,076	1,41		Algorithm converged.	1,03	1,95	0,0336		0,71		Algorithm converged.	0,51	0,97
	ACUTE CORONARY SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7	0,51		Algorithm converged.	0,13	2,03	-0,003		Algorithm converged.	-0,010	0,003		0,51		Algorithm converged.	0,13	2,02	0,3369			1,97		Algorithm converged.	0,49	7,85
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	AORTIC VALVE INCOMPETENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE		NE	NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	AORTIC VALVE SCLEROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005		0,76		Algorithm converged.	0,17	3,39	0,7211			1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009		1,56		Algorithm converged.	0,26	9,28	0,6271			0,64		Algorithm converged.	0,11	3,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTERIOSCLEROSIS CORONARY ARTERY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ATRIAL FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	ATRIAL TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ATRIAL THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BIFASCICULAR BLOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
	BRADYCARDIA	0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BUNDLE BRANCH BLOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BUNDLE BRANCH BLOCK LEFT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BUNDLE BRANCH BLOCK RIGHT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
	CARDIAC ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIAC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	7	0,8	1,46		Algorithm converged.	0,55	3,84	0,003		Algorithm converged.	-0,005	0,012	1,45		Algorithm converged.	0,55	3,80	0,4479		0,69		Algorithm converged.	0,26	1,80
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	5	0,8	2,74		Algorithm converged.	0,97	7,73	0,014		Algorithm converged.	0,000	0,028	2,70		Algorithm converged.	0,97	7,52	0,0577		0,37		Algorithm converged.	0,13	1,03
	CARDIAC FAILURE CONGESTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	CARDIOVASCULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIOVASCULAR INSUFFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONDUCTION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIASTOLIC DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor <= 1 cm																																
	EXTRASYSTOLES		51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.87480164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEART VALVE INCOMPETENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	HYPERTENSIVE HEART DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	LEFT VENTRICULAR DILATATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	LEFT VENTRICULAR DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEFT VENTRICULAR HYPERTROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	METABOLIC CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MITRAL VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MITRAL VALVE INCOMPETENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	MITRAL VALVE PROLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYOCARDIAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821801 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NODAL RHYTHM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALPITATIONS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075	0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	12	4,6	271	14,9	16	5,9	0,77		Algorithm converged.	0,36	1,67	-0,013		Algorithm converged.	-0,051	0,025	0,78		Algorithm converged.	0,38	1,63	0,5145		1,27		Algorithm converged.	0,61	2,64	
		1-3 positive nodes	891	50,0	39	4,4	905	49,7	41	4,5	0,96		Algorithm converged.	0,62	1,51	-0,002		Algorithm converged.	-0,021	0,018	0,97		Algorithm converged.	0,63	1,48	0,8749		1,04		Algorithm converged.	0,67	1,59	
		>= 4 positive nodes	582	32,6	24	4,1	604	33,2	20	3,3	1,26		Algorithm converged.	0,69	2,30	0,008		Algorithm converged.	-0,013	0,030	1,25		Algorithm converged.	0,70	2,23	0,4602		0,80		Algorithm converged.	0,45	1,44	
	PERICARDIAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	2	0,3	2,08		Algorithm converged.	0,38	11,42	0,004		Algorithm converged.	-0,005	0,012	2,08		Algorithm converged.	0,38	11,29	0,3980		0,48		Algorithm converged.	0,09	2,62	
	PRINZMETAL ANGINA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SINUS ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	SINUS BRADYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SINUS NODE DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,003		Algorithm converged.	-0,010	0,004	0,58		Algorithm converged.	0,17	1,98	0,3841		1,72		Algorithm converged.	0,51	5,87
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRESS CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPRAVENTRICULAR EXTRASYSTOLES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SUPRAVENTRICULAR TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	3	1,1	2,12		Algorithm converged.	0,52	8,56	0,012		Algorithm converged.	-0,010	0,034		2,09		Algorithm converged.	0,53	8,28	0,2927		0,48		Algorithm converged.	0,12	1,89
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	18	2,0	1,07		Algorithm converged.	0,56	2,06	0,001		Algorithm converged.	-0,012	0,015		1,07		Algorithm converged.	0,57	2,03	0,8306		0,93		Algorithm converged.	0,49	1,77
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	10	1,7	1,79		Algorithm converged.	0,81	3,94	0,013		Algorithm converged.	-0,004	0,030		1,76		Algorithm converged.	0,81	3,82	0,1499		0,57		Algorithm converged.	0,26	1,23
	TACHYCARDIA PAROXYSMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICUSPID VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRICUSPID VALVE INCOMPETENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	VENTRICULAR EXTRASYSTOLES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	VENTRICULAR FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)											
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CYSTIC FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHALANGEAL HYPOPLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYLORIC STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TYPE V HYPERLIPIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
EAR AND LABYRINTH DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,7454	0,81		Algorithm converged.	0,24	2,68
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	25	9,2	0,69		Algorithm converged.	0,36	1,31	-0,027		Algorithm converged.	-0,072	0,019	0,71		Algorithm converged.	0,39	1,29	0,2599		1,41		Algorithm converged.	0,78	2,54
		1-3 positive nodes	891	50,0	65	7,3	905	49,7	66	7,3	1,00		Algorithm converged.	0,70	1,43	0,000		Algorithm converged.	-0,024	0,024	1,00		Algorithm converged.	0,72	1,39	0,9985		1,00		Algorithm converged.	0,72	1,39
		>= 4 positive nodes	582	32,6	34	5,8	604	33,2	36	6,0	0,98		Algorithm converged.	0,60	1,59	-0,001		Algorithm converged.	-0,028	0,026	0,98		Algorithm converged.	0,62	1,54	0,9311		1,02		Algorithm converged.	0,65	1,61
	CERUMEN IMPACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONDUCTIVE DEAFNESS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DEAFNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30	
	DEAFNESS BILATERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEAFNESS UNILATERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EAR CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	EAR DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342			0,33		Algorithm converged.	0,03	3,15			
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EAR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	4	1,5	0,26		Algorithm converged.	0,03	2,33	-0,011		Algorithm converged.	-0,027	0,005	0,26		Algorithm converged.	0,03	2,32	0,2289		3,82		Algorithm converged.	0,43	33,98
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8	1,16		Algorithm converged.	0,42	3,22	0,001		Algorithm converged.	-0,007	0,010	1,16		Algorithm converged.	0,42	3,19	0,7723		0,86		Algorithm converged.	0,31	2,37
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	EXTERNAL EAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOACUSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	MENIERE'S DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MIDDLE EAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	OTOLITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTOTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRESBYACUSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TINNITUS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	21	2,3	0,82		Algorithm converged.	0,43	1,56	-0,004		Algorithm converged.	-0,017	0,009	0,82		Algorithm converged.	0,44	1,55	0,5443		1,22		Algorithm converged.	0,65	2,29
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	6	1,0	1,21		Algorithm converged.	0,41	3,63	0,002		Algorithm converged.	-0,010	0,014	1,21		Algorithm converged.	0,41	3,58	0,7296		0,83		Algorithm converged.	0,28	2,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	TYMPANIC MEMBRANE PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	VERTIGO	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	3	7,1	0,53		Algorithm converged.	0,08	3,33	-0,032		Algorithm converged.	-0,127	0,062		0,55		Algorithm converged.	0,10	3,13	0,4999	-	1,82		Algorithm converged.	0,32	10,40	
		0 positive nodes, tumor > 1 cm	259	14,5	12	4,6	271	14,9	11	4,1	1,15		Algorithm converged.	0,50	2,65	0,006		Algorithm converged.	-0,029	0,040		1,14		Algorithm converged.	0,51	2,54	0,7459		0,88		Algorithm converged.	0,39	1,95	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	29	3,3	905	49,7	31	3,4	0,95		Algorithm converged.	0,57	1,59	-0,002		Algorithm converged.	-0,018	0,015		0,95		Algorithm converged.	0,58	1,56	0,8406		1,05		Algorithm converged.	0,64	1,73
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	19	3,1	0,76		Algorithm converged.	0,38	1,53	-0,007		Algorithm converged.	-0,026	0,011		0,76		Algorithm converged.	0,39	1,51	0,4400		1,31		Algorithm converged.	0,66	2,58
	VERTIGO POSITIONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	VESTIBULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	3	1,1	2,12		Algorithm converged.	0,52	8,56	0,012		Algorithm converged.	-0,010	0,034	2,09		Algorithm converged.	0,53	8,28	0,2927		0,48		Algorithm converged.	0,12	1,89
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	13	1,4	0,70		Algorithm converged.	0,30	1,65	-0,004		Algorithm converged.	-0,014	0,006	0,70		Algorithm converged.	0,30	1,64	0,4140		1,42		Algorithm converged.	0,61	3,31
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	8	1,3	0,26		Algorithm converged.	0,05	1,21	-0,010		Algorithm converged.	-0,020	0,000	0,26		Algorithm converged.	0,06	1,22	0,0870		3,85		Algorithm converged.	0,82	18,07
	AUTOIMMUNE THYROIDITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CUSHING'S SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CUSHINGOID	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GOITRE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERPARATHYROIDISM PRIMARY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPROLACTINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOTHYROIDISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STEROID WITHDRAWAL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THYROID CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THYROID MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THYROID PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	13	25,5	42	2,3	10	23,8	1,09		Algorithm converged.	0,42	2,83	0,017		Algorithm converged.	-0,159	0,193	1,07		Algorithm converged.	0,52	2,19	0,8519	0,7310	0,93		Algorithm converged.	0,46	1,91
		0 positive nodes, tumor > 1 cm	259	14,5	63	24,3	271	14,9	74	27,3	0,86		Algorithm converged.	0,58	1,26	-0,030		Algorithm converged.	-0,104	0,045	0,89		Algorithm converged.	0,67	1,19	0,4339		1,12		Algorithm converged.	0,84	1,50
		1-3 positive nodes	891	50,0	244	27,4	905	49,7	240	26,5	1,04		Algorithm converged.	0,85	1,29	0,009		Algorithm converged.	-0,032	0,050	1,03		Algorithm converged.	0,89	1,20	0,6793		0,97		Algorithm converged.	0,83	1,13
		>= 4 positive nodes	582	32,6	135	23,2	604	33,2	128	21,2	1,12		Algorithm converged.	0,85	1,48	0,020		Algorithm converged.	-0,027	0,067	1,09		Algorithm converged.	0,88	1,35	0,4065		0,91		Algorithm converged.	0,74	1,13
	ABNORMAL SENSATION IN EYE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AMAUROSIS FUGAX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AMBLYOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASTHENOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASTIGMATISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLEPHARITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	BLEPHARITIS ALLERGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLEPHAROSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARACT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002		0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	CATARACT CORTICAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHALAZION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	CONJUNCTIVAL DEPOSIT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONJUNCTIVAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	CONJUNCTIVAL HYPERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVITIS ALLERGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	CORNEAL EXFOLIATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DACRYOSTENOSIS ACQUIRED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIPLOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRY EYE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	16	6,2	271	14,9	16	5,9	1,05		Algorithm converged.	0,51	2,14	0,003		Algorithm converged.	-0,038	0,043	1,05		Algorithm converged.	0,53	2,05	0,8949		0,96		Algorithm converged.	0,49	1,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	46	5,2	905	49,7	39	4,3	1,21		Algorithm converged.	0,78	1,87	0,009		Algorithm converged.	-0,011	0,028	1,20		Algorithm converged.	0,79	1,82	0,3952		0,83		Algorithm converged.	0,55	1,27
		>= 4 positive nodes	582	32,6	29	5,0	604	33,2	25	4,1	1,21		Algorithm converged.	0,70	2,10	0,008		Algorithm converged.	-0,015	0,032	1,20		Algorithm converged.	0,71	2,03	0,4866		0,83		Algorithm converged.	0,49	1,40
	ECTROPION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA OF EYELID	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	EYE ALLERGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	7	0,8	0,43		Algorithm converged.	0,11	1,68	-0,004		Algorithm converged.	-0,011	0,002	0,44		Algorithm converged.	0,11	1,68	0,2270		2,30		Algorithm converged.	0,60	8,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYE HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	6	0,7	1,02		Algorithm converged.	0,33	3,16	0,000		Algorithm converged.	-0,007	0,008	1,02		Algorithm converged.	0,33	3,14	0,9784		0,98		Algorithm converged.	0,32	3,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	EYE MOVEMENT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918			1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	7	0,8	1,60		Algorithm converged.	0,62	4,16	0,005		Algorithm converged.	-0,005	0,014		1,60		Algorithm converged.	0,62	4,10	0,3312			0,63		Algorithm converged.	0,24	1,61
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573			2,89		Algorithm converged.	0,30	27,71
	EYE PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006		1,52		Algorithm converged.	0,26	9,10	0,6442			0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013		1,73		Algorithm converged.	0,42	7,20	0,4517			0,58		Algorithm converged.	0,14	2,41
	EYE SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	EYELID FUNCTION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EYELID MARGIN CRUSTING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	EYELID OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	3	0,3	2,04		Algorithm converged.	0,51	8,18	0,003		Algorithm converged.	-0,003	0,010	2,03		Algorithm converged.	0,51	8,10	0,3151		0,49		Algorithm converged.	0,12	1,96
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	EYELID PTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYELID RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID SKIN DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EYELIDS PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOREIGN BODY SENSATION IN EYES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLAUCOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	IRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	KERATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATOCONUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	KERATOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LACRIMATION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LACRIMATION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LACRIMATION INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	7	16,7	0,67		Algorithm converged.	0,21	2,16	-0,049		Algorithm converged.	-0,192	0,094	0,71		Algorithm converged.	0,26	1,94	0,4995	0,0843	1,42		Algorithm converged.	0,52	3,89
		0 positive nodes, tumor > 1 cm	259	14,5	31	12,0	271	14,9	39	14,4	0,81		Algorithm converged.	0,49	1,34	-0,024		Algorithm converged.	-0,082	0,033	0,83		Algorithm converged.	0,54	1,29	0,4115		1,20		Algorithm converged.	0,77	1,87
		1-3 positive nodes	891	50,0	119	13,4	905	49,7	146	16,1	0,80		Algorithm converged.	0,62	1,04	-0,028		Algorithm converged.	-0,061	0,005	0,83		Algorithm converged.	0,66	1,04	0,0979		1,21		Algorithm converged.	0,97	1,51
		>= 4 positive nodes	582	32,6	72	12,4	604	33,2	55	9,1	1,41		Algorithm converged.	0,97	2,04	0,033		Algorithm converged.	-0,003	0,068	1,36		Algorithm converged.	0,97	1,89	0,0705		0,74		Algorithm converged.	0,53	1,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MACULAR OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	MEIBOMIAN GLAND DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METAMORPHOPSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NONINFECTIVE CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OCULAR HYPERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	2	0,2	3,58		Algorithm converged.	0,74	17,26	0,006		Algorithm converged.	-0,001	0,012		3,55		Algorithm converged.	0,74	17,07	0,1130		0,28		Algorithm converged.	0,06	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	OCULAR HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OCULAR TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPHTHALMOPLEGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OPTIC NERVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORBITAL GRANULOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAPILLOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERIORBITAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	PERIORBITAL SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHOTOPHOBIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 45.078386058 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHOTOPSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PTERYGIUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RETINAL VASCULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCLERAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCLERAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ULCERATIVE KERATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UVEITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERNAL KERATOCONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VISION BLURRED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	5	1,8	0,83		Algorithm converged.	0,22	3,14	-0,003		Algorithm converged.	-0,025	0,019	0,84		Algorithm converged.	0,23	3,08	0,7892		1,19		Algorithm converged.	0,32	4,40	
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	25	2,8	0,81		Algorithm converged.	0,45	1,47	-0,005		Algorithm converged.	-0,020	0,009	0,81		Algorithm converged.	0,45	1,45	0,4836		1,23		Algorithm converged.	0,69	2,20	
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	13	2,2	1,29		Algorithm converged.	0,61	2,70	0,006		Algorithm converged.	-0,012	0,024	1,28		Algorithm converged.	0,62	2,63	0,5070		0,78		Algorithm converged.	0,38	1,61	
	VISUAL ACUITY REDUCED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	4	0,4	2,04		Algorithm converged.	0,61	6,80	0,005		Algorithm converged.	-0,003	0,012	2,03		Algorithm converged.	0,61	6,72	0,2457		0,49		Algorithm converged.	0,15	1,63	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	VISUAL FIELD DEFECT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	VISUAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	5	1,8	1,48		Algorithm converged.	0,46	4,72	0,009		Algorithm converged.	-0,017	0,034	1,46		Algorithm converged.	0,47	4,56	0,5097		0,68		Algorithm converged.	0,22	2,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	7	0,8	2,80		Algorithm converged.	1,17	6,68	0,014		Algorithm converged.	0,003	0,025		2,76		Algorithm converged.	1,16	6,53	0,0211		0,36		Algorithm converged.	0,15	0,86
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	9	1,5	1,16		Algorithm converged.	0,47	2,87	0,002		Algorithm converged.	-0,012	0,017		1,15		Algorithm converged.	0,47	2,82	0,7546		0,87		Algorithm converged.	0,35	2,12
	VITREOUS DETACHMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VITREOUS FLOATERS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010		5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009		1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
	VITREOUS HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VITREOUS OPACITIES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	XEROPHTHALMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	49	96,1	42	2,3	37	88,1	3,31		Algorithm converged.	0,61	18,02	0,080		Algorithm converged.	-0,032	0,191	1,09		Algorithm converged.	0,96	1,23	0,1711	0,7578	0,92		Algorithm converged.	0,81	1,04
		0 positive nodes, tumor > 1 cm	259	14,5	250	96,5	271	14,9	246	90,8	2,82		Algorithm converged.	1,29	6,17	0,058		Algorithm converged.	0,016	0,099	1,06		Algorithm converged.	1,02	1,11	0,0067		0,94		Algorithm converged.	0,90	0,98
		1-3 positive nodes	891	50,0	837	93,9	905	49,7	812	89,7	1,78		Algorithm converged.	1,25	2,52	0,042		Algorithm converged.	0,017	0,067	1,05		Algorithm converged.	1,02	1,08	0,0011		0,96		Algorithm converged.	0,93	0,98
		>= 4 positive nodes	582	32,6	551	94,7	604	33,2	535	88,6	2,29		Algorithm converged.	1,48	3,56	0,061		Algorithm converged.	0,030	0,092	1,07		Algorithm converged.	1,03	1,11	0,0002		0,94		Algorithm converged.	0,90	0,97
	ABDOMINAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2	0,52		Algorithm converged.	0,13	2,09	-0,011		Algorithm converged.	-0,032	0,011	0,52		Algorithm converged.	0,13	2,07	0,3559		1,91		Algorithm converged.	0,48	7,56
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	10	1,1	0,61		Algorithm converged.	0,22	1,68	-0,004		Algorithm converged.	-0,013	0,004	0,61		Algorithm converged.	0,22	1,67	0,3355		1,64		Algorithm converged.	0,60	4,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	11	1,8	0,85		Algorithm converged.	0,35	2,06	-0,003		Algorithm converged.	-0,017	0,012	0,85		Algorithm converged.	0,35	2,03	0,7136		1,18		Algorithm converged.	0,49	2,82
	ABDOMINAL DISTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	9	3,3	0,81		Algorithm converged.	0,30	2,20	-0,006		Algorithm converged.	-0,035	0,023	0,81		Algorithm converged.	0,31	2,15	0,6781		1,23		Algorithm converged.	0,46	3,25
		1-3 positive nodes	891	50,0	32	3,6	905	49,7	18	2,0	1,84		Algorithm converged.	1,02	3,30	0,016		Algorithm converged.	0,001	0,031	1,81		Algorithm converged.	1,02	3,19	0,0422		0,55		Algorithm converged.	0,31	0,98
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	13	2,2	1,29		Algorithm converged.	0,61	2,70	0,006		Algorithm converged.	-0,012	0,024	1,28		Algorithm converged.	0,62	2,63	0,5070		0,78		Algorithm converged.	0,38	1,61
	ABDOMINAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	6	14,3	1,65		Algorithm converged.	0,55	4,92	0,073		Algorithm converged.	-0,082	0,228		1,51		Algorithm converged.	0,61	3,74	0,3733	0,8152	0,66		Algorithm converged.	0,27	1,64
		0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	27	10,0	1,10		Algorithm converged.	0,63	1,91	0,008		Algorithm converged.	-0,044	0,060		1,09		Algorithm converged.	0,66	1,79	0,7491		0,92		Algorithm converged.	0,56	1,52
		1-3 positive nodes	891	50,0	97	10,9	905	49,7	98	10,8	1,01		Algorithm converged.	0,75	1,35	0,001		Algorithm converged.	-0,028	0,029		1,01		Algorithm converged.	0,77	1,31	0,9685		0,99		Algorithm converged.	0,76	1,30
		>= 4 positive nodes	582	32,6	64	11,0	604	33,2	58	9,6	1,16		Algorithm converged.	0,80	1,69	0,014		Algorithm converged.	-0,021	0,049		1,15		Algorithm converged.	0,82	1,60	0,4300		0,87		Algorithm converged.	0,62	1,22
	ABDOMINAL PAIN LOWER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002	0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	ABDOMINAL PAIN UPPER	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	8	19,0	0,68		Algorithm converged.	0,22	2,05	-0,053		Algorithm converged.	-0,205	0,099	0,72		Algorithm converged.	0,28	1,82	0,4891	0,2596	1,39		Algorithm converged.	0,55	3,51						
		0 positive nodes, tumor > 1 cm	259	14,5	33	12,7	271	14,9	20	7,4	1,83		Algorithm converged.	1,02	3,29	0,054		Algorithm converged.	0,002	0,105	1,73		Algorithm converged.	1,02	2,93	0,0429		0,58		Algorithm converged.	0,34	0,98						
		1-3 positive nodes	891	50,0	90	10,1	905	49,7	80	8,8	1,16		Algorithm converged.	0,84	1,59	0,013		Algorithm converged.	-0,014	0,040	1,14		Algorithm converged.	0,86	1,52	0,3617		0,88		Algorithm converged.	0,66	1,17						
		>= 4 positive nodes	582	32,6	45	7,7	604	33,2	48	7,9	0,97		Algorithm converged.	0,64	1,48	-0,002		Algorithm converged.	-0,033	0,028	0,97		Algorithm converged.	0,66	1,44	0,8905		1,03		Algorithm converged.	0,70	1,52						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ABDOMINAL RIGIDITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ABNORMAL FAECES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACID PEPTIC DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AEROPHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ANAESTHESIA ORAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FISSURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	5	0,8	1,04		Algorithm converged.	0,30	3,60	0,000		Algorithm converged.	-0,010	0,011	1,04		Algorithm converged.	0,30	3,57	0,9530		0,96		Algorithm converged.	0,28	3,31
	ANAL FISTULA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	6	1,0	0,86		Algorithm converged.	0,26	2,85	-0,001		Algorithm converged.	-0,012	0,010	0,86		Algorithm converged.	0,27	2,82	0,8096		1,16		Algorithm converged.	0,35	3,77
	ANAL INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	ANAL PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002		0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	ANAL SKIN TAGS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGULAR CHEILITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	10	1,1	0,81		Algorithm converged.	0,32	2,06	-0,002		Algorithm converged.	-0,011	0,007	0,81		Algorithm converged.	0,32	2,05	0,6601		1,23		Algorithm converged.	0,49	3,10
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	ANORECTAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	ANORECTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	12	1,3	1,19		Algorithm converged.	0,55	2,58	0,002		Algorithm converged.	-0,009	0,014		1,18		Algorithm converged.	0,55	2,55	0,6638		0,84		Algorithm converged.	0,39	1,81
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	7	1,2	1,19		Algorithm converged.	0,43	3,30	0,002		Algorithm converged.	-0,011	0,015		1,19		Algorithm converged.	0,43	3,25	0,7400		0,84		Algorithm converged.	0,31	2,31
	APTYALISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASCITES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	BREATH ODOUR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHANGE OF BOWEL HABIT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHAPPED LIPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHEILITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	CHRONIC GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,004		Algorithm converged.	-0,010	0,001	0,20		Algorithm converged.	0,02	1,74	0,1453		4,92		Algorithm converged.	0,58	42,05
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	COLITIS ISCHAEMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	0 positive nodes, tumor <= 1 cm	51	2,9	14	27,5	42	2,3	14	33,3	0,76		Algorithm converged.	0,31	1,84	-0,059		Algorithm converged.	-0,247	0,129	0,82		Algorithm converged.	0,44	1,53	0,5381	0,6352	1,21		Algorithm converged.	0,65	2,25
		0 positive nodes, tumor > 1 cm	259	14,5	85	32,8	271	14,9	88	32,5	1,02		Algorithm converged.	0,71	1,46	0,003		Algorithm converged.	-0,076	0,083	1,01		Algorithm converged.	0,79	1,29	0,9323		0,99		Algorithm converged.	0,77	1,26
		1-3 positive nodes	891	50,0	261	29,3	905	49,7	270	29,8	0,97		Algorithm converged.	0,80	1,19	-0,005		Algorithm converged.	-0,048	0,037	0,98		Algorithm converged.	0,85	1,13	0,8016		1,02		Algorithm converged.	0,88	1,17
		>= 4 positive nodes	582	32,6	146	25,1	604	33,2	176	29,1	0,81		Algorithm converged.	0,63	1,05	-0,041		Algorithm converged.	-0,091	0,010	0,86		Algorithm converged.	0,71	1,04	0,1176		1,16		Algorithm converged.	0,96	1,40
	DENTAL CARIES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04						
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	4	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	38	74,5	42	2,3	22	52,4	2,66		Algorithm converged.	1,11	6,37	0,221		Algorithm converged.	0,029	0,414	1,42		Algorithm converged.	1,02	1,98	0,0364	0,2113	0,70		Algorithm converged.	0,51	0,98						
		0 positive nodes, tumor > 1 cm	259	14,5	188	72,6	271	14,9	141	52,0	2,44		Algorithm converged.	1,70	3,51	0,206		Algorithm converged.	0,125	0,286	1,40		Algorithm converged.	1,22	1,60	<.0001		0,72		Algorithm converged.	0,63	0,82						
		1-3 positive nodes	891	50,0	619	69,5	905	49,7	407	45,0	2,78		Algorithm converged.	2,29	3,38	0,245		Algorithm converged.	0,201	0,289	1,54		Algorithm converged.	1,42	1,68	<.0001		0,65		Algorithm converged.	0,60	0,70						
		>= 4 positive nodes	582	32,6	410	70,4	604	33,2	254	42,1	3,28		Algorithm converged.	2,58	4,18	0,284		Algorithm converged.	0,230	0,338	1,68		Algorithm converged.	1,50	1,87	<.0001		0,60		Algorithm converged.	0,54	0,66						
	DIARRHOEA HAEMORRHAGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM INTESTINAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULUM OESOPHAGEAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY MOUTH	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	3	7,1	0,81		Algorithm converged.	0,16	4,25	-0,013		Algorithm converged.	-0,114	0,089	0,82		Algorithm converged.	0,18	3,87	0,8057	-	1,21		Algorithm converged.	0,26	5,71
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	11	4,1	1,45		Algorithm converged.	0,65	3,23	0,017		Algorithm converged.	-0,020	0,054	1,43		Algorithm converged.	0,67	3,05	0,3588		0,70		Algorithm converged.	0,33	1,50
		1-3 positive nodes	891	50,0	59	6,6	905	49,7	65	7,2	0,92		Algorithm converged.	0,64	1,32	-0,006		Algorithm converged.	-0,029	0,018	0,92		Algorithm converged.	0,66	1,30	0,6396		1,08		Algorithm converged.	0,77	1,52
		>= 4 positive nodes	582	32,6	30	5,2	604	33,2	23	3,8	1,37		Algorithm converged.	0,79	2,39	0,013		Algorithm converged.	-0,010	0,037	1,35		Algorithm converged.	0,80	2,30	0,2638		0,74		Algorithm converged.	0,43	1,26
	DUODENAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	DUODENAL ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSCHEZIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	DYSPEPSIA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	8	19,0	0,36		Algorithm converged.	0,10	1,30	-0,112		Algorithm converged.	-0,252	0,028	0,41		Algorithm converged.	0,13	1,27	0,1233	0,1978	2,43		Algorithm converged.	0,79	7,51						
		0 positive nodes, tumor > 1 cm	259	14,5	33	12,7	271	14,9	43	15,9	0,77		Algorithm converged.	0,47	1,26	-0,031		Algorithm converged.	-0,091	0,028	0,80		Algorithm converged.	0,53	1,22	0,3064		1,25		Algorithm converged.	0,82	1,90						
		1-3 positive nodes	891	50,0	132	14,8	905	49,7	119	13,1	1,15		Algorithm converged.	0,88	1,50	0,017		Algorithm converged.	-0,015	0,049	1,13		Algorithm converged.	0,90	1,42	0,3091		0,89		Algorithm converged.	0,71	1,12						
		>= 4 positive nodes	582	32,6	74	12,7	604	33,2	76	12,6	1,01		Algorithm converged.	0,72	1,43	0,001		Algorithm converged.	-0,037	0,039	1,01		Algorithm converged.	0,75	1,36	0,9455		0,99		Algorithm converged.	0,73	1,33						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024		1,40		Algorithm converged.	0,32	6,17	0,6608			0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	30	3,4	905	49,7	26	2,9	1,18		Algorithm converged.	0,69	2,01	0,005		Algorithm converged.	-0,011	0,021		1,17		Algorithm converged.	0,70	1,97	0,5474			0,85		Algorithm converged.	0,51	1,43
		>= 4 positive nodes	582	32,6	22	3,8	604	33,2	15	2,5	1,54		Algorithm converged.	0,79	3,00	0,013		Algorithm converged.	-0,007	0,033		1,52		Algorithm converged.	0,80	2,90	0,2027			0,66		Algorithm converged.	0,34	1,25
	ENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506			0,48		Algorithm converged.	0,04	5,30
	ENTEROCOLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPIGASTRIC DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERUCTATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	FAECALOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAECES SOFT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	FLATULENCE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133992 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	5	1,8	0,83		Algorithm converged.	0,22	3,14	-0,003		Algorithm converged.	-0,025	0,019	0,84		Algorithm converged.	0,23	3,08	0,7892		1,19		Algorithm converged.	0,32	4,40	
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	19	2,1	0,96		Algorithm converged.	0,50	1,84	-0,001		Algorithm converged.	-0,014	0,012	0,96		Algorithm converged.	0,51	1,82	0,9059		1,04		Algorithm converged.	0,55	1,97	
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	8	1,3	1,17		Algorithm converged.	0,45	3,05	0,002		Algorithm converged.	-0,011	0,016	1,17		Algorithm converged.	0,45	3,01	0,7482		0,86		Algorithm converged.	0,33	2,20	
	FOOD POISONING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FREQUENT BOWEL MOVEMENTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FUNCTIONAL GASTROINTESTINAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC DILATATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71	
	GASTRIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTRIC MUCOSA ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	GASTRIC POLYPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007		0,35		Algorithm converged.	0,04	3,33	0,3603			2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875			0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	7	2,6	0,74		Algorithm converged.	0,23	2,37	-0,007		Algorithm converged.	-0,032	0,019	0,75		Algorithm converged.	0,24	2,33	0,6151		1,34		Algorithm converged.	0,43	4,16
		1-3 positive nodes	891	50,0	28	3,1	905	49,7	16	1,8	1,80		Algorithm converged.	0,97	3,36	0,014		Algorithm converged.	-0,001	0,028	1,78		Algorithm converged.	0,97	3,26	0,0634		0,56		Algorithm converged.	0,31	1,03
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	8	1,3	1,44		Algorithm converged.	0,57	3,59	0,006		Algorithm converged.	-0,009	0,020	1,43		Algorithm converged.	0,58	3,52	0,4406		0,70		Algorithm converged.	0,28	1,73
	GASTRITIS EROSIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	GASTROINTESTINAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7	0,51		Algorithm converged.	0,13	2,03	-0,003		Algorithm converged.	-0,010	0,003	0,51		Algorithm converged.	0,13	2,02	0,3369		1,97		Algorithm converged.	0,49	7,85
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	7	1,2	0,89		Algorithm converged.	0,30	2,66	-0,001		Algorithm converged.	-0,013	0,011	0,89		Algorithm converged.	0,30	2,63	0,8325		1,12		Algorithm converged.	0,38	3,33
	GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL MOTILITY DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL MUCOSAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	6	0,7	1,70		Algorithm converged.	0,62	4,70	0,005		Algorithm converged.	-0,004	0,013	1,69		Algorithm converged.	0,62	4,64	0,3060		0,59		Algorithm converged.	0,22	1,62
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	2	0,3	3,66		Algorithm converged.	0,76	17,71	0,009		Algorithm converged.	-0,001	0,019	3,63		Algorithm converged.	0,76	17,41	0,1067		0,28		Algorithm converged.	0,06	1,32
	GASTROINTESTINAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	GASTROINTESTINAL SOUNDS ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE		
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE		
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
	GASTROINTESTINAL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	GASTROOESOPHAGEAL REFLUX DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83	
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	12	4,4	1,14		Algorithm converged.	0,51	2,55	0,006		Algorithm converged.	-0,030	0,042	1,13		Algorithm converged.	0,53	2,44	0,7484		0,88		Algorithm converged.	0,41	1,90	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	42	4,7	905	49,7	41	4,5	1,04		Algorithm converged.	0,67	1,62	0,002		Algorithm converged.	-0,018	0,021	1,04		Algorithm converged.	0,68	1,58	0,8531		0,96		Algorithm converged.	0,63	1,46
		>= 4 positive nodes	582	32,6	34	5,8	604	33,2	28	4,6	1,28		Algorithm converged.	0,76	2,13	0,012		Algorithm converged.	-0,013	0,037	1,26		Algorithm converged.	0,77	2,05	0,3520		0,79		Algorithm converged.	0,49	1,29
	GINGIVAL ATROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023		3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04	
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	4	0,4	2,56		Algorithm converged.	0,80	8,18	0,007		Algorithm converged.	-0,001	0,015		2,54		Algorithm converged.	0,80	8,07	0,1141		0,39		Algorithm converged.	0,12	1,25	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	7	1,2	0,29		Algorithm converged.	0,06	1,42	-0,008		Algorithm converged.	-0,018	0,002		0,30		Algorithm converged.	0,06	1,42	0,1285		3,37		Algorithm converged.	0,70	16,17	
	GINGIVAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	5	1,8	0,21		Algorithm converged.	0,02	1,78	-0,015		Algorithm converged.	-0,032	0,003		0,21		Algorithm converged.	0,02	1,78	0,1520		4,78		Algorithm converged.	0,56	40,63	
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	7	0,8	1,31		Algorithm converged.	0,49	3,53	0,002		Algorithm converged.	-0,006	0,011		1,31		Algorithm converged.	0,49	3,49	0,5948		0,77		Algorithm converged.	0,29	2,05	
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	5	0,8	1,04		Algorithm converged.	0,30	3,60	0,000		Algorithm converged.	-0,010	0,011		1,04		Algorithm converged.	0,30	3,57	0,9530		0,96		Algorithm converged.	0,28	3,31	
	GINGIVAL SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801847 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVAL ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	6	0,7	0,17		Algorithm converged.	0,02	1,40	-0,006		Algorithm converged.	-0,011	0,000	0,17		Algorithm converged.	0,02	1,40	0,0998		5,91		Algorithm converged.	0,71	48,97
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	GLOSSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLOSSODYNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	HAEMATOCHEZIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	5	0,6	0,61		Algorithm converged.	0,14	2,55	-0,002		Algorithm converged.	-0,008	0,004		0,61		Algorithm converged.	0,15	2,54	0,4968		1,64		Algorithm converged.	0,39	6,85
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	2	0,3	3,66		Algorithm converged.	0,76	17,71	0,009		Algorithm converged.	-0,001	0,019		3,63		Algorithm converged.	0,76	17,41	0,1067		0,28		Algorithm converged.	0,06	1,32
	HAEMORRHOIDAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029		1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	7	0,8	0,87		Algorithm converged.	0,29	2,60	-0,001		Algorithm converged.	-0,009	0,007		0,87		Algorithm converged.	0,29	2,58	0,8026		1,15		Algorithm converged.	0,39	3,40

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	6	1,0	2,10		Algorithm converged.	0,78	5,63	0,011		Algorithm converged.	-0,003	0,025	2,08		Algorithm converged.	0,78	5,49	0,1414		0,48		Algorithm converged.	0,18	1,28
	HAEMORRHOIDS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	2	4,8	1,25		Algorithm converged.	0,20	7,85	0,011		Algorithm converged.	-0,080	0,102	1,24		Algorithm converged.	0,22	7,05	0,8121	-	0,81		Algorithm converged.	0,14	4,62
		0 positive nodes, tumor > 1 cm	259	14,5	26	10,0	271	14,9	15	5,5	1,90		Algorithm converged.	0,98	3,68	0,045		Algorithm converged.	-0,001	0,091	1,81		Algorithm converged.	0,98	3,35	0,0567		0,55		Algorithm converged.	0,30	1,02
		1-3 positive nodes	891	50,0	67	7,5	905	49,7	44	4,9	1,59		Algorithm converged.	1,07	2,36	0,027		Algorithm converged.	0,004	0,049	1,55		Algorithm converged.	1,07	2,24	0,0205		0,65		Algorithm converged.	0,45	0,94
		>= 4 positive nodes	582	32,6	38	6,5	604	33,2	35	5,8	1,14		Algorithm converged.	0,71	1,82	0,007		Algorithm converged.	-0,020	0,035	1,13		Algorithm converged.	0,72	1,76	0,5990		0,89		Algorithm converged.	0,57	1,38
	HIATUS HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPERAESTHESIA TEETH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506			0,48		Algorithm converged.	0,04	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERCHLORHYDRIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOAESTHESIA ORAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IMPAIRED GASTRIC EMPTYING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGUINAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IRRITABLE BOWEL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	LARGE INTESTINAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LARGE INTESTINE POLYP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIP DRY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIP EROSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	LIP OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	LIP PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIP SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	LIP ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	LOOSE TOOTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	MELAENA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MOUTH HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MOUTH ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	9	3,3	1,17		Algorithm converged.	0,47	2,93	0,005		Algorithm converged.	-0,026	0,037	1,16		Algorithm converged.	0,48	2,81	0,7385		0,86		Algorithm converged.	0,36	2,08
		1-3 positive nodes	891	50,0	28	3,1	905	49,7	32	3,5	0,89		Algorithm converged.	0,53	1,48	-0,004		Algorithm converged.	-0,021	0,013	0,89		Algorithm converged.	0,54	1,46	0,6430		1,13		Algorithm converged.	0,68	1,85
		>= 4 positive nodes	582	32,6	15	2,6	604	33,2	17	2,8	0,91		Algorithm converged.	0,45	1,85	-0,002		Algorithm converged.	-0,021	0,016	0,92		Algorithm converged.	0,46	1,82	0,8010		1,09		Algorithm converged.	0,55	2,17
	NAUSEA	0 positive nodes, tumor <= 1 cm	51	2,9	38	74,5	42	2,3	25	59,5	1,99		Algorithm converged.	0,82	4,80	0,150		Algorithm converged.	-0,041	0,340	1,25		Algorithm converged.	0,93	1,68	0,1378	0,5676	0,80		Algorithm converged.	0,59	1,07
		0 positive nodes, tumor > 1 cm	259	14,5	179	69,1	271	14,9	174	64,2	1,25		Algorithm converged.	0,87	1,79	0,049		Algorithm converged.	-0,031	0,129	1,08		Algorithm converged.	0,95	1,21	0,2313		0,93		Algorithm converged.	0,82	1,05
		1-3 positive nodes	891	50,0	621	69,7	905	49,7	589	65,1	1,23		Algorithm converged.	1,01	1,50	0,046		Algorithm converged.	0,003	0,089	1,07		Algorithm converged.	1,00	1,14	0,0372		0,93		Algorithm converged.	0,88	1,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	395	67,9	604	33,2	399	66,1	1,09		Algorithm converged.	0,85	1,38	0,018		Algorithm converged.	-0,035	0,072	1,03		Algorithm converged.	0,95	1,11	0,5076		0,97		Algorithm converged.	0,90	1,05
	NONINFECTIVE GINGIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ODYNOPHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	5	0,6	2,25		Algorithm converged.	0,78	6,50	0,007		Algorithm converged.	-0,002	0,016	2,23		Algorithm converged.	0,78	6,41	0,1345		0,45		Algorithm converged.	0,16	1,28	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004	0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37	
	OEDEMA MOUTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OESOPHAGEAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	OESOPHAGEAL SPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OESOPHAGEAL STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OESOPHAGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	6	0,7	1,87		Algorithm converged.	0,69	5,09	0,006		Algorithm converged.	-0,003	0,015	1,86		Algorithm converged.	0,69	5,01	0,2186		0,54		Algorithm converged.	0,20	1,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	11	1,8	1,04		Algorithm converged.	0,45	2,41	0,001		Algorithm converged.	-0,015	0,016	1,04		Algorithm converged.	0,45	2,38	0,9300		0,96		Algorithm converged.	0,42	2,21
	ORAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL DYSAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	ORAL LICHEN PLANUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL MUCOSA HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ORAL MUCOSAL BLISTERING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL MUCOSAL ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL MUCOSAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2	0,52		Algorithm converged.	0,13	2,09	-0,011		Algorithm converged.	-0,032	0,011	0,52		Algorithm converged.	0,13	2,07	0,3559		1,91		Algorithm converged.	0,48	7,56
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	16	1,8	0,76		Algorithm converged.	0,36	1,61	-0,004		Algorithm converged.	-0,016	0,007	0,76		Algorithm converged.	0,36	1,60	0,4728		1,31		Algorithm converged.	0,62	2,76
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	12	2,0	0,95		Algorithm converged.	0,42	2,17	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,42	2,14	0,9039		1,05		Algorithm converged.	0,47	2,36
	OVERFLOW DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PANCREATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA ORAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010	5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAROTID GLAND ENLARGEMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PEPTIC ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 46.532527544 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,070		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERIODONTAL DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	PROCTALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	5	1,8	0,83		Algorithm converged.	0,22	3,14	-0,003		Algorithm converged.	-0,025	0,019	0,84		Algorithm converged.	0,23	3,08	0,7892		1,19		Algorithm converged.	0,32	4,40
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	4	0,4	3,34		Algorithm converged.	1,08	10,27	0,010		Algorithm converged.	0,001	0,019	3,30		Algorithm converged.	1,08	10,09	0,0361		0,30		Algorithm converged.	0,10	0,93
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	8	1,3	0,91		Algorithm converged.	0,33	2,52	-0,001		Algorithm converged.	-0,014	0,011	0,91		Algorithm converged.	0,33	2,49	0,8513		1,10		Algorithm converged.	0,40	3,02
	RECTAL TENESMUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	REFLUX GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETCHING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALIVARY GLAND PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALIVARY HYPERSECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SMALL INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	STOMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	15	29,4	42	2,3	8	19,0	1,77		Algorithm converged.	0,67	4,71	0,104		Algorithm converged.	-0,069	0,276	1,54		Algorithm converged.	0,73	3,28	0,2592	0,7046	0,65		Algorithm converged.	0,30	1,38
		0 positive nodes, tumor > 1 cm	259	14,5	77	29,7	271	14,9	75	27,7	1,11		Algorithm converged.	0,76	1,61	0,021		Algorithm converged.	-0,056	0,098	1,07		Algorithm converged.	0,82	1,41	0,6012		0,93		Algorithm converged.	0,71	1,22
		1-3 positive nodes	891	50,0	254	28,5	905	49,7	208	23,0	1,34		Algorithm converged.	1,08	1,65	0,055		Algorithm converged.	0,015	0,096	1,24		Algorithm converged.	1,06	1,45	0,0076		0,81		Algorithm converged.	0,69	0,94
		>= 4 positive nodes	582	32,6	169	29,0	604	33,2	139	23,0	1,37		Algorithm converged.	1,05	1,78	0,060		Algorithm converged.	0,010	0,110	1,26		Algorithm converged.	1,04	1,53	0,0185		0,79		Algorithm converged.	0,65	0,96

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	STRAWBERRY TONGUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE				
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE				
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE				
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE				
	SUBILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE				
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE				

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SWOLLEN TONGUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONGUE BLISTERING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TONGUE COATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 42.426716 29 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	TONGUE DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TONGUE DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONGUE ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TONGUE PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TONGUE ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	TOOTH DEVELOPMENT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOOTH DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH IMPACTED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH LOSS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOOTHACHE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	24	2,7	0,97		Algorithm converged.	0,54	1,74	-0,001		Algorithm converged.	-0,015	0,014	0,97		Algorithm converged.	0,55	1,71	0,9254		1,03		Algorithm converged.	0,58	1,81
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	16	2,6	0,71		Algorithm converged.	0,33	1,54	-0,008		Algorithm converged.	-0,025	0,009	0,71		Algorithm converged.	0,33	1,52	0,3835		1,40		Algorithm converged.	0,66	2,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UMBILICAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	VOMITING	0 positive nodes, tumor <= 1 cm	51	2,9	13	25,5	42	2,3	11	26,2	0,96		Algorithm converged.	0,38	2,45	-0,007		Algorithm converged.	-0,186	0,172		0,97		Algorithm converged.	0,49	1,94	0,9388	0,9248	1,03		Algorithm converged.	0,51	2,05
		0 positive nodes, tumor > 1 cm	259	14,5	88	34,0	271	14,9	79	29,2	1,25		Algorithm converged.	0,87	1,81	0,048		Algorithm converged.	-0,031	0,127		1,17		Algorithm converged.	0,91	1,50	0,2327		0,86		Algorithm converged.	0,67	1,10
		1-3 positive nodes	891	50,0	294	33,0	905	49,7	279	30,8	1,10		Algorithm converged.	0,91	1,35	0,022		Algorithm converged.	-0,021	0,065		1,07		Algorithm converged.	0,93	1,23	0,3245		0,93		Algorithm converged.	0,82	1,07
		>= 4 positive nodes	582	32,6	210	36,1	604	33,2	197	32,6	1,17		Algorithm converged.	0,92	1,48	0,035		Algorithm converged.	-0,019	0,089		1,11		Algorithm converged.	0,94	1,30	0,2090		0,90		Algorithm converged.	0,77	1,06
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	47	92,2	42	2,3	36	85,7	1,96		Algorithm converged.	0,51	7,46	0,064		Algorithm converged.	-0,065	0,193		1,08		Algorithm converged.	0,93	1,25	0,3344	0,9538	0,93		Algorithm converged.	0,80	1,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	228	88,0	271	14,9	229	84,5	1,35		Algorithm converged.	0,82	2,22	0,035		Algorithm converged.	-0,023	0,094	1,04		Algorithm converged.	0,97	1,12	0,2379		0,96		Algorithm converged.	0,90	1,03
		1-3 positive nodes	891	50,0	757	85,0	905	49,7	739	81,7	1,27		Algorithm converged.	0,99	1,63	0,033		Algorithm converged.	-0,001	0,067	1,04		Algorithm converged.	1,00	1,08	0,0607		0,96		Algorithm converged.	0,92	1,00
		>= 4 positive nodes	582	32,6	468	80,4	604	33,2	472	78,1	1,15		Algorithm converged.	0,87	1,52	0,023		Algorithm converged.	-0,023	0,069	1,03		Algorithm converged.	0,97	1,09	0,3355		0,97		Algorithm converged.	0,92	1,03
	ADVERSE DRUG REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APPLICATION SITE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	17	33,3	42	2,3	13	31,0	1,12		Algorithm converged.	0,46	2,68	0,024		Algorithm converged.	-0,167	0,214	1,08		Algorithm converged.	0,59	1,95	0,8073	0,7290	0,93		Algorithm converged.	0,51	1,68
		0 positive nodes, tumor > 1 cm	259	14,5	56	21,6	271	14,9	53	19,6	1,13		Algorithm converged.	0,74	1,73	0,021		Algorithm converged.	-0,048	0,090	1,11		Algorithm converged.	0,79	1,55	0,5569		0,90		Algorithm converged.	0,65	1,26
		1-3 positive nodes	891	50,0	201	22,6	905	49,7	184	20,3	1,14		Algorithm converged.	0,91	1,43	0,022		Algorithm converged.	-0,016	0,060	1,11		Algorithm converged.	0,93	1,32	0,2504		0,90		Algorithm converged.	0,75	1,08
		>= 4 positive nodes	582	32,6	106	18,2	604	33,2	117	19,4	0,93		Algorithm converged.	0,69	1,24	-0,012		Algorithm converged.	-0,056	0,033	0,94		Algorithm converged.	0,74	1,19	0,6101		1,06		Algorithm converged.	0,84	1,35
	AXILLARY PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	12	1,3	1,19		Algorithm converged.	0,55	2,58	0,002		Algorithm converged.	-0,009	0,014		1,18		Algorithm converged.	0,55	2,55	0,6638		0,84		Algorithm converged.	0,39	1,81
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	9	1,5	1,51		Algorithm converged.	0,64	3,56	0,007		Algorithm converged.	-0,008	0,023		1,50		Algorithm converged.	0,65	3,48	0,3462		0,67		Algorithm converged.	0,29	1,55
	CATHETER SITE BRUISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CATHETER SITE ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CATHETER SITE INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CATHETER SITE IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATHETER SITE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	8	0,9	1,40		Algorithm converged.	0,56	3,50	0,004		Algorithm converged.	-0,006	0,013	1,40		Algorithm converged.	0,56	3,46	0,4699		0,72		Algorithm converged.	0,29	1,77
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004	0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37
	CATHETER SITE PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEST DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	6	2,2	1,05		Algorithm converged.	0,33	3,29	0,001		Algorithm converged.	-0,024	0,026	1,05		Algorithm converged.	0,34	3,20	0,9368		0,96		Algorithm converged.	0,31	2,93
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	15	1,7	0,95		Algorithm converged.	0,45	1,97	-0,001		Algorithm converged.	-0,013	0,011	0,95		Algorithm converged.	0,46	1,95	0,8848		1,05		Algorithm converged.	0,51	2,17
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	11	1,8	0,56		Algorithm converged.	0,21	1,53	-0,008		Algorithm converged.	-0,021	0,006	0,57		Algorithm converged.	0,21	1,52	0,2591		1,77		Algorithm converged.	0,66	4,75
	CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047	0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	6	2,2	1,05		Algorithm converged.	0,33	3,29	0,001		Algorithm converged.	-0,024	0,026	1,05		Algorithm converged.	0,34	3,20	0,9368		0,96		Algorithm converged.	0,31	2,93
		1-3 positive nodes	891	50,0	28	3,1	905	49,7	28	3,1	1,02		Algorithm converged.	0,60	1,73	0,000		Algorithm converged.	-0,016	0,017	1,02		Algorithm converged.	0,61	1,70	0,9527		0,98		Algorithm converged.	0,59	1,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	20	3,3	0,83		Algorithm converged.	0,42	1,61	-0,006		Algorithm converged.	-0,025	0,014	0,83		Algorithm converged.	0,43	1,59	0,5733		1,20		Algorithm converged.	0,63	2,30
	CHILLS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047	0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	15	5,5	1,20		Algorithm converged.	0,59	2,45	0,010		Algorithm converged.	-0,030	0,051	1,19		Algorithm converged.	0,60	2,32	0,6197		0,84		Algorithm converged.	0,43	1,65
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	37	4,1	0,90		Algorithm converged.	0,56	1,46	-0,004		Algorithm converged.	-0,022	0,014	0,91		Algorithm converged.	0,57	1,44	0,6738		1,10		Algorithm converged.	0,70	1,75
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	23	3,8	0,85		Algorithm converged.	0,46	1,58	-0,005		Algorithm converged.	-0,026	0,016	0,86		Algorithm converged.	0,47	1,56	0,6132		1,17		Algorithm converged.	0,64	2,12
	COMPLICATION ASSOCIATED WITH DEVICE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CREPITATIONS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CRYING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 46.532527544 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYST RUPTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSPLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENANTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EXERCISE TOLERANCE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	FACE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	7	2,6	0,74		Algorithm converged.	0,23	2,37	-0,007		Algorithm converged.	-0,032	0,019	0,75		Algorithm converged.	0,24	2,33	0,6151		1,34		Algorithm converged.	0,43	4,16
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	15	1,7	0,67		Algorithm converged.	0,30	1,51	-0,005		Algorithm converged.	-0,016	0,005	0,68		Algorithm converged.	0,31	1,50	0,3363		1,48		Algorithm converged.	0,67	3,27
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	10	1,7	0,72		Algorithm converged.	0,27	1,91	-0,005		Algorithm converged.	-0,018	0,009	0,73		Algorithm converged.	0,28	1,90	0,5137		1,38		Algorithm converged.	0,53	3,59
	FACIAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	FAT NECROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	27	52,9	42	2,3	18	42,9	1,50		Algorithm converged.	0,66	3,41	0,101		Algorithm converged.	-0,102	0,304	1,24		Algorithm converged.	0,80	1,91	0,3406	0,3799	0,81		Algorithm converged.	0,52	1,25
		0 positive nodes, tumor > 1 cm	259	14,5	134	51,7	271	14,9	124	45,8	1,27		Algorithm converged.	0,90	1,79	0,060		Algorithm converged.	-0,025	0,145	1,13		Algorithm converged.	0,95	1,35	0,1690		0,88		Algorithm converged.	0,74	1,05
		1-3 positive nodes	891	50,0	421	47,3	905	49,7	414	45,7	1,06		Algorithm converged.	0,88	1,28	0,015		Algorithm converged.	-0,031	0,061	1,03		Algorithm converged.	0,94	1,14	0,5228		0,97		Algorithm converged.	0,88	1,07
		>= 4 positive nodes	582	32,6	284	48,8	604	33,2	250	41,4	1,35		Algorithm converged.	1,07	1,70	0,074		Algorithm converged.	0,018	0,131	1,18		Algorithm converged.	1,04	1,34	0,0106		0,85		Algorithm converged.	0,75	0,96
	FEELING ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEELING COLD	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	FEELING HOT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	FEELING JITTERY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEELING OF BODY TEMPERATURE CHANGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOREIGN BODY REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GAIT DISTURBANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959			1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 58.941926146 is greater than the limit of 0.0001. The convergence is questionable.	-0,066	0,062	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83						
	GENERALISED OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	8	0,9	0,38		Algorithm converged.	0,10	1,43	-0,005		Algorithm converged.	-0,013	0,002	0,38		Algorithm converged.	0,10	1,43	0,1529		2,63		Algorithm converged.	0,70	9,86						
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21						
	HUNGER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERPYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHERMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	8	0,9	0,25		Algorithm converged.	0,05	1,19	-0,007		Algorithm converged.	-0,013	0,000	0,25		Algorithm converged.	0,05	1,19	0,0824		3,94		Algorithm converged.	0,84	18,49
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOTHERMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ILL-DEFINED DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023		3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	11	1,2	0,55		Algorithm converged.	0,20	1,50	-0,005		Algorithm converged.	-0,014	0,004		0,55		Algorithm converged.	0,21	1,49	0,2425		1,80		Algorithm converged.	0,67	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014	1,56		Algorithm converged.	0,44	5,49	0,4912		0,64		Algorithm converged.	0,18	2,26
	ILLNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IMPAIRED HEALING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	IMPLANT SITE INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INDURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	INFLUENZA LIKE ILLNESS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	3	7,1	0,26		Algorithm converged.	0,03	2,60	-0,052		Algorithm converged.	-0,139	0,035	0,27		Algorithm converged.	0,03	2,54	0,2550	-	3,64		Algorithm converged.	0,39	33,74
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	15	5,5	1,05		Algorithm converged.	0,50	2,19	0,003		Algorithm converged.	-0,037	0,042	1,05		Algorithm converged.	0,52	2,10	0,8984		0,96		Algorithm converged.	0,48	1,92
		1-3 positive nodes	891	50,0	56	6,3	905	49,7	50	5,5	1,15		Algorithm converged.	0,77	1,70	0,008		Algorithm converged.	-0,014	0,029	1,14		Algorithm converged.	0,79	1,65	0,4946		0,88		Algorithm converged.	0,61	1,27
		>= 4 positive nodes	582	32,6	28	4,8	604	33,2	23	3,8	1,28		Algorithm converged.	0,73	2,24	0,010		Algorithm converged.	-0,013	0,033	1,26		Algorithm converged.	0,74	2,17	0,3958		0,79		Algorithm converged.	0,46	1,36
	INFUSION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	5	1,8	0,41		Algorithm converged.	0,08	2,15	-0,011		Algorithm converged.	-0,030	0,009	0,42		Algorithm converged.	0,08	2,14	0,2952		2,39		Algorithm converged.	0,47	12,21
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	INJECTION SITE BRUISING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INJECTION SITE DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	INJECTION SITE ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	INJECTION SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INJECTION SITE PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	INJECTION SITE PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INJECTION SITE THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOCALISED OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	5	1,8	0,62		Algorithm converged.	0,15	2,64	-0,007		Algorithm converged.	-0,028	0,014	0,63		Algorithm converged.	0,15	2,60	0,5209		1,59		Algorithm converged.	0,38	6,60
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	3	0,5	2,09		Algorithm converged.	0,52	8,38	0,005		Algorithm converged.	-0,005	0,015	2,08		Algorithm converged.	0,52	8,26	0,3001		0,48		Algorithm converged.	0,12	1,92
	MALAISE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	3	7,1	0,26		Algorithm converged.	0,03	2,60	-0,052		Algorithm converged.	-0,139	0,035	0,27		Algorithm converged.	0,03	2,54	0,2550	-	3,64		Algorithm converged.	0,39	33,74
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	18	6,6	0,86		Algorithm converged.	0,43	1,75	-0,009		Algorithm converged.	-0,050	0,033	0,87		Algorithm converged.	0,45	1,69	0,6857		1,15		Algorithm converged.	0,59	2,23
		1-3 positive nodes	891	50,0	25	2,8	905	49,7	32	3,5	0,79		Algorithm converged.	0,46	1,34	-0,007		Algorithm converged.	-0,023	0,009	0,79		Algorithm converged.	0,47	1,33	0,3787		1,26		Algorithm converged.	0,75	2,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	20	3,3	0,72		Algorithm converged.	0,36	1,44	-0,009		Algorithm converged.	-0,028	0,010		0,73		Algorithm converged.	0,37	1,42	0,3523		1,38		Algorithm converged.	0,70	2,70
	MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	MEDICAL DEVICE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	METAPLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	MUCOSAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006		1,52		Algorithm converged.	0,26	9,10	0,6442			0,66		Algorithm converged.	0,11	3,92	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	MUCOSAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-		2,43		Algorithm converged.	0,23	25,86	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	1	0,4	5,31		Algorithm converged.	0,62	45,80	0,016		Algorithm converged.	-0,003	0,034	5,23		Algorithm converged.	0,62	44,48	0,1297		0,19		Algorithm converged.	0,02	1,63
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	13	1,4	1,17		Algorithm converged.	0,56	2,48	0,002		Algorithm converged.	-0,009	0,014	1,17		Algorithm converged.	0,56	2,45	0,6730		0,85		Algorithm converged.	0,41	1,78
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	6	1,0	1,92		Algorithm converged.	0,71	5,23	0,009		Algorithm converged.	-0,005	0,023	1,90		Algorithm converged.	0,71	5,11	0,2020		0,53		Algorithm converged.	0,20	1,41
	MUCOSAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	16	31,4	42	2,3	13	31,0	1,02		Algorithm converged.	0,42	2,46	0,004		Algorithm converged.	-0,185	0,193	1,01		Algorithm converged.	0,55	1,86	0,9653	0,4457	0,99		Algorithm converged.	0,54	1,81
		0 positive nodes, tumor > 1 cm	259	14,5	62	23,9	271	14,9	57	21,0	1,18		Algorithm converged.	0,79	1,78	0,029		Algorithm converged.	-0,042	0,100	1,14		Algorithm converged.	0,83	1,56	0,4234		0,88		Algorithm converged.	0,64	1,21
		1-3 positive nodes	891	50,0	216	24,2	905	49,7	152	16,8	1,59		Algorithm converged.	1,26	2,00	0,074		Algorithm converged.	0,037	0,112	1,44		Algorithm converged.	1,20	1,74	0,0001		0,69		Algorithm converged.	0,58	0,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	111	19,1	604	33,2	93	15,4	1,29		Algorithm converged.	0,96	1,75	0,037		Algorithm converged.	-0,006	0,080	1,24		Algorithm converged.	0,96	1,59	0,0945		0,81		Algorithm converged.	0,63	1,04
	MUCOSAL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NODULE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30	
	NON-CARDIAC CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	10	1,1	0,20		Algorithm converged.	0,04	0,92	-0,009		Algorithm converged.	-0,016	-0,001		0,20		Algorithm converged.	0,04	0,92	0,0393		4,92		Algorithm converged.	1,08	22,40	
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006		0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69	
	OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148		1,24		Algorithm converged.	0,37	4,09	0,7294	0,7529	0,81		Algorithm converged.	0,24	2,68	
		0 positive nodes, tumor > 1 cm	259	14,5	23	8,9	271	14,9	21	7,7	1,16		Algorithm converged.	0,63	2,15	0,011		Algorithm converged.	-0,036	0,058		1,15		Algorithm converged.	0,65	2,02	0,6373		0,87		Algorithm converged.	0,50	1,54	
		1-3 positive nodes	891	50,0	52	5,8	905	49,7	53	5,9	1,00		Algorithm converged.	0,67	1,48	0,000		Algorithm converged.	-0,022	0,021		1,00		Algorithm converged.	0,69	1,44	0,9854		1,00		Algorithm converged.	0,69	1,45	
		>= 4 positive nodes	582	32,6	30	5,2	604	33,2	39	6,5	0,79		Algorithm converged.	0,48	1,29	-0,013		Algorithm converged.	-0,040	0,014		0,80		Algorithm converged.	0,50	1,27	0,3394		1,25		Algorithm converged.	0,79	1,99	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	8	19,0	1,17		Algorithm converged.	0,42	3,24	0,025		Algorithm converged.	-0,139	0,189	1,13		Algorithm converged.	0,50	2,56	0,7647	0,8202	0,88		Algorithm converged.	0,39	1,99
		0 positive nodes, tumor > 1 cm	259	14,5	52	20,1	271	14,9	67	24,7	0,76		Algorithm converged.	0,51	1,15	-0,046		Algorithm converged.	-0,117	0,024	0,81		Algorithm converged.	0,59	1,12	0,2019		1,23		Algorithm converged.	0,89	1,70
		1-3 positive nodes	891	50,0	158	17,7	905	49,7	184	20,3	0,84		Algorithm converged.	0,67	1,07	-0,026		Algorithm converged.	-0,062	0,010	0,87		Algorithm converged.	0,72	1,06	0,1614		1,15		Algorithm converged.	0,95	1,39
		>= 4 positive nodes	582	32,6	83	14,3	604	33,2	109	18,0	0,76		Algorithm converged.	0,55	1,03	-0,038		Algorithm converged.	-0,080	0,004	0,79		Algorithm converged.	0,61	1,03	0,0781		1,27		Algorithm converged.	0,97	1,64
	PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	7	2,6	2,65		Algorithm converged.	1,08	6,50	0,040		Algorithm converged.	0,004	0,075	2,54		Algorithm converged.	1,07	6,03	0,0343		0,39		Algorithm converged.	0,17	0,93
		1-3 positive nodes	891	50,0	61	6,8	905	49,7	65	7,2	0,95		Algorithm converged.	0,66	1,36	-0,003		Algorithm converged.	-0,027	0,020	0,95		Algorithm converged.	0,68	1,34	0,7804		1,05		Algorithm converged.	0,75	1,47
		>= 4 positive nodes	582	32,6	46	7,9	604	33,2	41	6,8	1,18		Algorithm converged.	0,76	1,82	0,011		Algorithm converged.	-0,019	0,041	1,16		Algorithm converged.	0,78	1,75	0,4618		0,86		Algorithm converged.	0,57	1,29
	PERIPHERAL SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	4	1,5	1,31		Algorithm converged.	0,35	4,95	0,005		Algorithm converged.	-0,018	0,027	1,31		Algorithm converged.	0,36	4,82	0,6865		0,76		Algorithm converged.	0,21	2,82
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	22	2,4	0,78		Algorithm converged.	0,41	1,48	-0,005		Algorithm converged.	-0,019	0,008	0,78		Algorithm converged.	0,42	1,47	0,4483		1,27		Algorithm converged.	0,68	2,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	10	1,7	0,93		Algorithm converged.	0,38	2,31	-0,001		Algorithm converged.	-0,015	0,013	0,93		Algorithm converged.	0,38	2,28	0,8810		1,07		Algorithm converged.	0,44	2,62
	PUNCTURE SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	14	27,5	42	2,3	6	14,3	2,27		Algorithm converged.	0,79	6,56	0,132		Algorithm converged.	-0,030	0,294	1,92		Algorithm converged.	0,81	4,56	0,1388	0,2620	0,52		Algorithm converged.	0,22	1,24
		0 positive nodes, tumor > 1 cm	259	14,5	50	19,3	271	14,9	61	22,5	0,82		Algorithm converged.	0,54	1,25	-0,032		Algorithm converged.	-0,101	0,037	0,86		Algorithm converged.	0,61	1,20	0,3659		1,17		Algorithm converged.	0,84	1,63
		1-3 positive nodes	891	50,0	176	19,8	905	49,7	171	18,9	1,06		Algorithm converged.	0,84	1,34	0,009		Algorithm converged.	-0,028	0,045	1,05		Algorithm converged.	0,87	1,26	0,6452		0,96		Algorithm converged.	0,79	1,16
		>= 4 positive nodes	582	32,6	119	20,4	604	33,2	108	17,9	1,18		Algorithm converged.	0,88	1,58	0,026		Algorithm converged.	-0,019	0,070	1,14		Algorithm converged.	0,90	1,45	0,2619		0,87		Algorithm converged.	0,69	1,11
	SCAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SECRETION DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SENSATION OF FOREIGN BODY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SUPRAPUBIC PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	SWELLING FACE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016	0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	2	0,2	3,06		Algorithm converged.	0,62	15,21	0,005		Algorithm converged.	-0,002	0,011	3,05		Algorithm converged.	0,62	15,06	0,1717		0,33		Algorithm converged.	0,07	1,62
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	TEMPERATURE INTOLERANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TEMPERATURE REGULATION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDERNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THIRST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455			0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009		2,54		Algorithm converged.	0,49	13,05	0,2646			0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860			1,45		Algorithm converged.	0,24	8,62
	ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	UNEVALUABLE EVENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	2	0,2	4,61		Algorithm converged.	0,99	21,38	0,008		Algorithm converged.	0,001	0,015		4,57		Algorithm converged.	0,99	21,10	0,0515		0,22		Algorithm converged.	0,05	1,01	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	VASCULAR DEVICE OCCLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VESSEL PUNCTURE SITE BRUISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	XEROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	1	0,1	7,16		Algorithm converged.	0,88	58,30	0,007		Algorithm converged.	0,001	0,013	7,11		Algorithm converged.	0,88	57,67	0,0663		0,14		Algorithm converged.	0,02	1,14
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	12	4,4	0,60		Algorithm converged.	0,23	1,55	-0,017		Algorithm converged.	-0,049	0,014	0,61		Algorithm converged.	0,24	1,53	0,2910		1,64		Algorithm converged.	0,66	4,10
		1-3 positive nodes	891	50,0	29	3,3	905	49,7	29	3,2	1,02		Algorithm converged.	0,60	1,71	0,001		Algorithm converged.	-0,016	0,017	1,02		Algorithm converged.	0,61	1,69	0,9519		0,98		Algorithm converged.	0,59	1,63
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	19	3,1	0,93		Algorithm converged.	0,48	1,80	-0,002		Algorithm converged.	-0,022	0,017	0,93		Algorithm converged.	0,49	1,77	0,8216		1,08		Algorithm converged.	0,57	2,05
	BILIARY COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CHOLECYSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLECYSTITIS CHRONIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CHOLESTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GALLBLADDER POLYP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008	4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC CYTOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FUNCTION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	11	1,2	0,46		Algorithm converged.	0,16	1,33	-0,007		Algorithm converged.	-0,015	0,002	0,46		Algorithm converged.	0,16	1,32	0,1503		2,17		Algorithm converged.	0,76	6,21
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	8	1,3	0,78		Algorithm converged.	0,27	2,25	-0,003		Algorithm converged.	-0,015	0,009	0,78		Algorithm converged.	0,27	2,23	0,6407		1,28		Algorithm converged.	0,45	3,68
	HEPATIC PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC STEATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	3	0,3	2,72		Algorithm converged.	0,72	10,30	0,006		Algorithm converged.	-0,002	0,013	2,71		Algorithm converged.	0,72	10,18	0,1401		0,37		Algorithm converged.	0,10	1,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	4	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATOBILIARY DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HEPATOTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERBILIRUBINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPERTRANSAMINASAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LIVER DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	LIVER INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	OCULAR ICTERUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	18	6,6	0,86		Algorithm converged.	0,43	1,75	-0,009		Algorithm converged.	-0,050	0,033	0,87		Algorithm converged.	0,45	1,69	0,6857		1,15		Algorithm converged.	0,59	2,23
		1-3 positive nodes	891	50,0	47	5,3	905	49,7	41	4,5	1,17		Algorithm converged.	0,76	1,80	0,007		Algorithm converged.	-0,013	0,027	1,16		Algorithm converged.	0,77	1,75	0,4653		0,86		Algorithm converged.	0,57	1,29
		>= 4 positive nodes	582	32,6	34	5,8	604	33,2	21	3,5	1,72		Algorithm converged.	0,99	3,00	0,024		Algorithm converged.	0,000	0,048	1,68		Algorithm converged.	0,99	2,86	0,0559		0,60		Algorithm converged.	0,35	1,01
	ALLERGIC OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ALLERGY TO ANIMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ANAPHYLACTIC REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002		0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DECREASED IMMUNE RESPONSIVENESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029	1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	3	0,3	3,07		Algorithm converged.	0,83	11,37	0,007		Algorithm converged.	-0,001	0,014	3,05		Algorithm converged.	0,83	11,22	0,0938		0,33		Algorithm converged.	0,09	1,21
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	5	0,8	1,67		Algorithm converged.	0,54	5,13	0,005		Algorithm converged.	-0,006	0,017	1,66		Algorithm converged.	0,55	5,05	0,3712		0,60		Algorithm converged.	0,20	1,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOOD ALLERGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	12	4,4	0,69		Algorithm converged.	0,28	1,71	-0,013		Algorithm converged.	-0,046	0,019	0,70		Algorithm converged.	0,29	1,68	0,4215		1,43		Algorithm converged.	0,60	3,45
		1-3 positive nodes	891	50,0	24	2,7	905	49,7	27	3,0	0,90		Algorithm converged.	0,52	1,57	-0,003		Algorithm converged.	-0,018	0,012	0,90		Algorithm converged.	0,53	1,55	0,7117		1,11		Algorithm converged.	0,64	1,90
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	13	2,2	1,53		Algorithm converged.	0,75	3,14	0,011		Algorithm converged.	-0,007	0,030	1,52		Algorithm converged.	0,76	3,04	0,2409		0,66		Algorithm converged.	0,33	1,32
	IMMUNE SYSTEM DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED HYPERSENSITIVITY REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEASONAL ALLERGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007		0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	3	0,3	3,07		Algorithm converged.	0,83	11,37	0,007		Algorithm converged.	-0,001	0,014		3,05		Algorithm converged.	0,83	11,22	0,0938		0,33		Algorithm converged.	0,09	1,21
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	3	0,5	2,09		Algorithm converged.	0,52	8,38	0,005		Algorithm converged.	-0,005	0,015		2,08		Algorithm converged.	0,52	8,26	0,3001		0,48		Algorithm converged.	0,12	1,92
	SERUM SICKNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	31	60,8	42	2,3	26	61,9	0,95		Algorithm converged.	0,41	2,21	-0,011		Algorithm converged.	-0,210	0,188	0,98		Algorithm converged.	0,71	1,36	0,9120	0,2908	1,02		Algorithm converged.	0,74	1,41
		0 positive nodes, tumor > 1 cm	259	14,5	164	63,3	271	14,9	177	65,3	0,92		Algorithm converged.	0,64	1,31	-0,020		Algorithm converged.	-0,102	0,062	0,97		Algorithm converged.	0,85	1,10	0,6323		1,03		Algorithm converged.	0,91	1,17
		1-3 positive nodes	891	50,0	562	63,1	905	49,7	518	57,2	1,28		Algorithm converged.	1,06	1,54	0,058		Algorithm converged.	0,013	0,104	1,10		Algorithm converged.	1,02	1,19	0,0117		0,91		Algorithm converged.	0,84	0,98
		>= 4 positive nodes	582	32,6	327	56,2	604	33,2	335	55,5	1,03		Algorithm converged.	0,82	1,30	0,007		Algorithm converged.	-0,049	0,064	1,01		Algorithm converged.	0,92	1,12	0,8023		0,99		Algorithm converged.	0,89	1,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ABDOMINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS JAW	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS LIMB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	
	ABSCESS ORAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACARODERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ACTINOMYCOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ADENOVIRAL CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARTHRITIS INFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASCARIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	BACTERIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506			0,48		Algorithm converged.	0,04	5,30
	BACTERIAL VAGINOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERIAL VULVOVAGINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BARTHOLINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BETA HAEMOLYTIC STREPTOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BODY TINEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BOTRYOMYCOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	BRONCHIOLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	4	9,5	0,19		Algorithm converged.	0,02	1,77	-0,076		Algorithm converged.	-0,172	0,021	0,21		Algorithm converged.	0,02	1,77	0,1502	-	4,86		Algorithm converged.	0,56	41,82
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	12	4,4	0,60		Algorithm converged.	0,23	1,55	-0,017		Algorithm converged.	-0,049	0,014	0,61		Algorithm converged.	0,24	1,53	0,2910		1,64		Algorithm converged.	0,66	4,10
		1-3 positive nodes	891	50,0	32	3,6	905	49,7	35	3,9	0,93		Algorithm converged.	0,57	1,51	-0,003		Algorithm converged.	-0,020	0,015	0,93		Algorithm converged.	0,58	1,49	0,7577		1,08		Algorithm converged.	0,67	1,72
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	22	3,6	0,80		Algorithm converged.	0,42	1,51	-0,007		Algorithm converged.	-0,027	0,013	0,80		Algorithm converged.	0,43	1,49	0,4871		1,25		Algorithm converged.	0,67	2,32
	BRONCHITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BULLOUS IMPETIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BURN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CAMPYLOBACTER INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CANDIDA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011		0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	9	1,0	1,70		Algorithm converged.	0,74	3,92	0,007		Algorithm converged.	-0,004	0,018		1,69		Algorithm converged.	0,74	3,85	0,2090		0,59		Algorithm converged.	0,26	1,34
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	7	1,2	1,04		Algorithm converged.	0,36	2,98	0,000		Algorithm converged.	-0,012	0,013		1,04		Algorithm converged.	0,37	2,94	0,9443		0,96		Algorithm converged.	0,34	2,73
	CARBUNCLE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATHETER SITE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CATHETER SITE PUSTULE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011		0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35	
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	15	1,7	1,36		Algorithm converged.	0,69	2,68	0,006		Algorithm converged.	-0,007	0,019		1,35		Algorithm converged.	0,70	2,63	0,3700		0,74		Algorithm converged.	0,38	1,43	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	14	2,3	0,89		Algorithm converged.	0,41	1,93	-0,003		Algorithm converged.	-0,019	0,014	0,89		Algorithm converged.	0,41	1,91	0,7635		1,12		Algorithm converged.	0,52	2,41
	CELLULITIS ORBITAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHEST WALL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHRONIC SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHRONIC TONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE						
	CLOSTRIDIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	CLOSTRIDIUM DIFFICILE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 46.553252754 4 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,070		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	4	9,5	1,03		Algorithm converged.	0,26	4,12	0,003		Algorithm converged.	-0,118	0,123		1,03		Algorithm converged.	0,30	3,59	0,9637	-	0,97		Algorithm converged.	0,28	3,39
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	19	7,0	0,93		Algorithm converged.	0,47	1,83	-0,004		Algorithm converged.	-0,047	0,038		0,94		Algorithm converged.	0,50	1,76	0,8379		1,07		Algorithm converged.	0,57	2,01
		1-3 positive nodes	891	50,0	60	6,7	905	49,7	45	5,0	1,38		Algorithm converged.	0,93	2,05	0,018		Algorithm converged.	-0,004	0,039		1,35		Algorithm converged.	0,93	1,97	0,1132		0,74		Algorithm converged.	0,51	1,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	28	4,8	604	33,2	25	4,1	1,17		Algorithm converged.	0,67	2,03	0,007		Algorithm converged.	-0,017	0,030	1,16		Algorithm converged.	0,69	1,97	0,5760		0,86		Algorithm converged.	0,51	1,46
	CONJUNCTIVITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	3	7,1	1,11		Algorithm converged.	0,23	5,24	0,007		Algorithm converged.	-0,100	0,114	1,10		Algorithm converged.	0,26	4,64	0,8987	-	0,91		Algorithm converged.	0,22	3,84
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	9	3,3	1,17		Algorithm converged.	0,47	2,93	0,005		Algorithm converged.	-0,026	0,037	1,16		Algorithm converged.	0,48	2,81	0,7385		0,86		Algorithm converged.	0,36	2,08
		1-3 positive nodes	891	50,0	31	3,5	905	49,7	17	1,9	1,88		Algorithm converged.	1,03	3,43	0,016		Algorithm converged.	0,001	0,031	1,85		Algorithm converged.	1,03	3,32	0,0387		0,54		Algorithm converged.	0,30	0,97
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	19	3,1	0,98		Algorithm converged.	0,51	1,89	-0,001		Algorithm converged.	-0,020	0,019	0,98		Algorithm converged.	0,52	1,85	0,9582		1,02		Algorithm converged.	0,54	1,92
	DENGUE FEVER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DERMATITIS INFECTED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATOPHYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	DEVICE RELATED SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
	DIARRHOEA INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821801 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIENTAMOEBA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DISSEMINATED TUBERCULOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 58.941926146 is greater than the limit of 0.0001. The convergence is questionable.	-0,066	0,062	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	DIVERTICULITIS INTESTINAL PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EAR INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	8	0,9	0,13		Algorithm converged.	0,02	1,01	-0,008		Algorithm converged.	-0,014	-0,001	0,13		Algorithm converged.	0,02	1,01	0,0514		7,88		Algorithm converged.	0,99	62,84
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	ENDOCARDITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)		PLACEBO (N=1822)		PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTERITIS INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROBIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	4	0,4	2,30		Algorithm converged.	0,71	7,49	0,006		Algorithm converged.	-0,002	0,014		2,29		Algorithm converged.	0,71	7,39	0,1677		0,44		Algorithm converged.	0,14	1,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	1	0,2	7,34		Algorithm converged.	0,90	59,85	0,010		Algorithm converged.	0,001	0,020		7,26		Algorithm converged.	0,90	58,86	0,0632		0,14		Algorithm converged.	0,02	1,12	
	ESCHERICHIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ESCHERICHIA URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	6	0,7	0,68		Algorithm converged.	0,19	2,40	-0,002		Algorithm converged.	-0,009	0,005	0,68		Algorithm converged.	0,19	2,39	0,5448		1,48		Algorithm converged.	0,42	5,22
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	9	1,5	0,46		Algorithm converged.	0,14	1,49	-0,008		Algorithm converged.	-0,020	0,004	0,46		Algorithm converged.	0,14	1,49	0,1957		2,17		Algorithm converged.	0,67	7,00
	EYELID FOLLICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EYELID INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOLLICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029	1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	7	0,8	2,05		Algorithm converged.	0,82	5,10	0,008		Algorithm converged.	-0,002	0,018	2,03		Algorithm converged.	0,82	5,01	0,1238		0,49		Algorithm converged.	0,20	1,21
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014	1,56		Algorithm converged.	0,44	5,49	0,4912		0,64		Algorithm converged.	0,18	2,26
	FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	2	0,3	3,14		Algorithm converged.	0,63	15,60	0,007		Algorithm converged.	-0,002	0,016	3,11		Algorithm converged.	0,63	15,36	0,1632		0,32		Algorithm converged.	0,07	1,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FUNGAL OESOPHAGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FUNGAL PHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	FUNGAL SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	3	0,3	3,07		Algorithm converged.	0,83	11,37	0,007		Algorithm converged.	-0,001	0,014		3,05		Algorithm converged.	0,83	11,22	0,0938		0,33		Algorithm converged.	0,09	1,21						
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004		0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FURUNCLE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007		0,35		Algorithm converged.	0,04	3,33	0,3603			2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7	0,51		Algorithm converged.	0,13	2,03	-0,003		Algorithm converged.	-0,010	0,003		0,51		Algorithm converged.	0,13	2,02	0,3369			1,97		Algorithm converged.	0,49	7,85
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	GASTRIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016	0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	22	2,4	0,87		Algorithm converged.	0,47	1,63	-0,003		Algorithm converged.	-0,017	0,011	0,88		Algorithm converged.	0,48	1,61	0,6722		1,14		Algorithm converged.	0,62	2,09
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	8	1,3	1,17		Algorithm converged.	0,45	3,05	0,002		Algorithm converged.	-0,011	0,016	1,17		Algorithm converged.	0,45	3,01	0,7482		0,86		Algorithm converged.	0,33	2,20
	GASTROENTERITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	GASTROINTESTINAL FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	GASTROINTESTINAL VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL HERPES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	GENITAL HERPES SIMPLEX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL INFECTION FEMALE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENITAL INFECTION FUNGAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	GENITOURINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GINGIVAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	19	2,1	0,85		Algorithm converged.	0,44	1,67	-0,003		Algorithm converged.	-0,016	0,010	0,86		Algorithm converged.	0,44	1,65	0,6419		1,17		Algorithm converged.	0,61	2,26
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	8	1,3	1,17		Algorithm converged.	0,45	3,05	0,002		Algorithm converged.	-0,011	0,016	1,17		Algorithm converged.	0,45	3,01	0,7482		0,86		Algorithm converged.	0,33	2,20
	GROIN ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	H1N1 INFLUENZA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HELICOBACTER INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	HEPATITIS B REACTIVATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES OPHTHALMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	7	0,8	0,72		Algorithm converged.	0,23	2,29	-0,002		Algorithm converged.	-0,010	0,005		0,73		Algorithm converged.	0,23	2,28	0,5825		1,38		Algorithm converged.	0,44	4,33

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HERPES VIRUS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	6	0,7	2,05		Algorithm converged.	0,76	5,47	0,007		Algorithm converged.	-0,002	0,016	2,03		Algorithm converged.	0,77	5,39	0,1545		0,49		Algorithm converged.	0,19	1,31
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	HERPES ZOSTER	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793		0,61		Algorithm converged.	0,06	6,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	11	4,1	0,66		Algorithm converged.	0,25	1,72	-0,014		Algorithm converged.	-0,044	0,017		0,67		Algorithm converged.	0,26	1,69	0,3925		1,50		Algorithm converged.	0,59	3,81	
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	20	2,2	0,86		Algorithm converged.	0,45	1,65	-0,003		Algorithm converged.	-0,016	0,010		0,86		Algorithm converged.	0,46	1,64	0,6527		1,16		Algorithm converged.	0,61	2,20	
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	18	3,0	0,63		Algorithm converged.	0,29	1,34	-0,011		Algorithm converged.	-0,028	0,007		0,63		Algorithm converged.	0,30	1,33	0,2287		1,58		Algorithm converged.	0,75	3,31	
	HORDEOLUM	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023		3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04	
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	11	1,2	0,74		Algorithm converged.	0,29	1,84	-0,003		Algorithm converged.	-0,013	0,006		0,74		Algorithm converged.	0,30	1,83	0,5123		1,35		Algorithm converged.	0,55	3,35	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	8	1,3	0,52		Algorithm converged.	0,15	1,72	-0,006		Algorithm converged.	-0,018	0,005		0,52		Algorithm converged.	0,16	1,71	0,2819		1,93		Algorithm converged.	0,58	6,37	
	IMPETIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCISION SITE CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTED BITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	2	0,7	2,11		Algorithm converged.	0,38	11,62	0,008		Algorithm converged.	-0,010	0,026	2,09		Algorithm converged.	0,39	11,33	0,3914		0,48		Algorithm converged.	0,09	2,59
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	13	1,4	1,41		Algorithm converged.	0,69	2,90	0,006		Algorithm converged.	-0,006	0,018	1,41		Algorithm converged.	0,69	2,85	0,3447		0,71		Algorithm converged.	0,35	1,44
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	12	2,0	0,69		Algorithm converged.	0,28	1,69	-0,006		Algorithm converged.	-0,021	0,008	0,69		Algorithm converged.	0,28	1,68	0,4158		1,45		Algorithm converged.	0,60	3,51
	INFLUENZA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	7	2,6	0,89		Algorithm converged.	0,30	2,70	-0,003		Algorithm converged.	-0,029	0,024	0,90		Algorithm converged.	0,31	2,63	0,8430		1,12		Algorithm converged.	0,38	3,27
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	30	3,3	0,77		Algorithm converged.	0,45	1,34	-0,007		Algorithm converged.	-0,023	0,008	0,78		Algorithm converged.	0,46	1,33	0,3598		1,28		Algorithm converged.	0,75	2,19
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	24	4,0	0,68		Algorithm converged.	0,36	1,30	-0,012		Algorithm converged.	-0,033	0,008	0,69		Algorithm converged.	0,37	1,29	0,2459		1,45		Algorithm converged.	0,78	2,69
	LABYRINTHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	3	1,1	1,05		Algorithm converged.	0,21	5,23	0,001		Algorithm converged.	-0,018	0,019	1,05		Algorithm converged.	0,21	5,14	0,9555		0,96		Algorithm converged.	0,19	4,69
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	9	1,0	0,79		Algorithm converged.	0,29	2,13	-0,002		Algorithm converged.	-0,011	0,007	0,79		Algorithm converged.	0,30	2,11	0,6385		1,27		Algorithm converged.	0,47	3,38
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48
	LARYNGOPHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIP INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003		0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	LOCALISED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024		1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	2	0,2	4,61		Algorithm converged.	0,99	21,38	0,008		Algorithm converged.	0,001	0,015		4,57		Algorithm converged.	0,99	21,10	0,0515		0,22		Algorithm converged.	0,05	1,01
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	4	0,7	1,30		Algorithm converged.	0,35	4,86	0,002		Algorithm converged.	-0,008	0,012		1,30		Algorithm converged.	0,35	4,81	0,6970		0,77		Algorithm converged.	0,21	2,86
	LOWER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	1	0,4	5,31		Algorithm converged.	0,62	45,80	0,016		Algorithm converged.	-0,003	0,034		5,23		Algorithm converged.	0,62	44,48	0,1297		0,19		Algorithm converged.	0,02	1,63
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	9	1,0	1,36		Algorithm converged.	0,57	3,24	0,004		Algorithm converged.	-0,006	0,013		1,35		Algorithm converged.	0,57	3,20	0,4891		0,74		Algorithm converged.	0,31	1,74
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004		0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37
	LYMPH GLAND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	LYMPHANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	MASTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	9	1,0	1,70		Algorithm converged.	0,74	3,92	0,007		Algorithm converged.	-0,004	0,018	1,69		Algorithm converged.	0,74	3,85	0,2090		0,59		Algorithm converged.	0,26	1,34
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	8	1,3	0,91		Algorithm converged.	0,33	2,52	-0,001		Algorithm converged.	-0,014	0,011	0,91		Algorithm converged.	0,33	2,49	0,8513		1,10		Algorithm converged.	0,40	3,02
	MORAXELLA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	MUCOSAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908			0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002		0,26		Algorithm converged.	0,03	2,31	0,2269			3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUMPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MYCOBACTERIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYRINGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	12	1,3	0,93		Algorithm converged.	0,41	2,12	-0,001		Algorithm converged.	-0,011	0,009		0,93		Algorithm converged.	0,41	2,10	0,8633		1,07		Algorithm converged.	0,48	2,42
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	5	0,8	1,88		Algorithm converged.	0,63	5,65	0,007		Algorithm converged.	-0,005	0,020		1,87		Algorithm converged.	0,63	5,54	0,2600		0,54		Algorithm converged.	0,18	1,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL HERPES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	NASAL VESTIBULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASOPHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	8	19,0	0,68		Algorithm converged.	0,22	2,05	-0,053		Algorithm converged.	-0,205	0,099	0,72		Algorithm converged.	0,28	1,82	0,4891	0,4116	1,39		Algorithm converged.	0,55	3,51
		0 positive nodes, tumor > 1 cm	259	14,5	42	16,2	271	14,9	31	11,4	1,50		Algorithm converged.	0,91	2,47	0,048		Algorithm converged.	-0,011	0,107	1,42		Algorithm converged.	0,92	2,18	0,1131		0,71		Algorithm converged.	0,46	1,09
		1-3 positive nodes	891	50,0	115	12,9	905	49,7	115	12,7	1,02		Algorithm converged.	0,77	1,34	0,002		Algorithm converged.	-0,029	0,033	1,02		Algorithm converged.	0,80	1,29	0,8993		0,98		Algorithm converged.	0,77	1,25
		>= 4 positive nodes	582	32,6	70	12,0	604	33,2	60	9,9	1,24		Algorithm converged.	0,86	1,79	0,021		Algorithm converged.	-0,015	0,057	1,21		Algorithm converged.	0,87	1,68	0,2495		0,83		Algorithm converged.	0,60	1,14
	NEUTROPENIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008	4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	OESOPHAGEAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OMPHALITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOMYCOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	ORAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011		0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	23	2,5	0,57		Algorithm converged.	0,29	1,13	-0,011		Algorithm converged.	-0,024	0,002		0,57		Algorithm converged.	0,29	1,13	0,1065		1,74		Algorithm converged.	0,89	3,42
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	7	1,2	1,04		Algorithm converged.	0,36	2,98	0,000		Algorithm converged.	-0,012	0,013		1,04		Algorithm converged.	0,37	2,94	0,9443		0,96		Algorithm converged.	0,34	2,73
	ORAL FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	1	0,1	7,16		Algorithm converged.	0,88	58,30	0,007		Algorithm converged.	0,001	0,013		7,11		Algorithm converged.	0,88	57,67	0,0663		0,14		Algorithm converged.	0,02	1,14
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	4	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORAL HERPES	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	8	3,0	0,78		Algorithm converged.	0,27	2,28	-0,006		Algorithm converged.	-0,034	0,021		0,78		Algorithm converged.	0,28	2,23	0,6493		1,27		Algorithm converged.	0,45	3,62
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	17	1,9	0,96		Algorithm converged.	0,48	1,90	-0,001		Algorithm converged.	-0,013	0,012		0,96		Algorithm converged.	0,49	1,88	0,8962		1,05		Algorithm converged.	0,53	2,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	6	1,0	1,21		Algorithm converged.	0,41	3,63	0,002		Algorithm converged.	-0,010	0,014		1,21		Algorithm converged.	0,41	3,58	0,7296		0,83		Algorithm converged.	0,28	2,44
	ORAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	OROPHARYNGITIS FUNGAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	OTITIS EXTERNA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OTITIS MEDIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	OTITIS MEDIA ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OTITIS MEDIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLOMA VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	2	4,8	1,70		Algorithm converged.	0,30	9,78	0,031		Algorithm converged.	-0,067	0,129		1,65		Algorithm converged.	0,32	8,55	0,5528	-	0,61		Algorithm converged.	0,12	3,15
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	6	2,2	2,72		Algorithm converged.	1,04	7,11	0,036		Algorithm converged.	0,002	0,069		2,62		Algorithm converged.	1,03	6,64	0,0430		0,38		Algorithm converged.	0,15	0,97
		1-3 positive nodes	891	50,0	36	4,0	905	49,7	20	2,2	1,86		Algorithm converged.	1,07	3,24	0,018		Algorithm converged.	0,002	0,034		1,83		Algorithm converged.	1,07	3,13	0,0282		0,55		Algorithm converged.	0,32	0,94
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	12	2,0	1,04		Algorithm converged.	0,46	2,33	0,001		Algorithm converged.	-0,015	0,017		1,04		Algorithm converged.	0,47	2,29	0,9268		0,96		Algorithm converged.	0,44	2,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAROTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PELVIC INFLAMMATORY DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PERICORONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIODONTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009		1,52		Algorithm converged.	0,43	5,38	0,5131			0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014		2,59		Algorithm converged.	0,51	13,32	0,2533			0,39		Algorithm converged.	0,08	1,98
	PERIPHERAL NERVE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERTUSSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	10	3,7	1,83		Algorithm converged.	0,82	4,08	0,029		Algorithm converged.	-0,009	0,066	1,78		Algorithm converged.	0,83	3,81	0,1387		0,56		Algorithm converged.	0,26	1,20
		1-3 positive nodes	891	50,0	37	4,2	905	49,7	39	4,3	0,96		Algorithm converged.	0,61	1,52	-0,002		Algorithm converged.	-0,020	0,017	0,96		Algorithm converged.	0,62	1,50	0,8690		1,04		Algorithm converged.	0,67	1,61
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	18	3,0	1,04		Algorithm converged.	0,54	2,02	0,001		Algorithm converged.	-0,018	0,021	1,04		Algorithm converged.	0,55	1,97	0,9100		0,96		Algorithm converged.	0,51	1,83
	PHARYNGITIS BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHARYNGITIS STREPTOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGOTONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHLEBITIS INFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PILONIDAL CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PLEURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	PNEUMOCYSTIS JIROVECII PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	5	1,8	1,05		Algorithm converged.	0,30	3,66	0,001		Algorithm converged.	-0,022	0,024		1,05		Algorithm converged.	0,31	3,57	0,9424		0,96		Algorithm converged.	0,28	3,26
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	21	2,3	0,72		Algorithm converged.	0,37	1,41	-0,006		Algorithm converged.	-0,019	0,007		0,73		Algorithm converged.	0,38	1,40	0,3378		1,38		Algorithm converged.	0,72	2,66
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	7	1,2	2,88		Algorithm converged.	1,20	6,90	0,021		Algorithm converged.	0,004	0,038		2,82		Algorithm converged.	1,19	6,65	0,0181		0,36		Algorithm converged.	0,15	0,84
	PNEUMONIA ASPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE					NE	NE					
	PNEUMONIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999				Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE					NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA CHLAMYDIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	PSEUDOMEMBRANOUS COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PSEUDOMONAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMONAS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY TUBERCULOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULPITIS DENTAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk								
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PURULENT DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PUSTULE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PYODERMA STREPTOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
	RADIATION SITE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE					NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE					NE	NE					
	RASH PUSTULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	6	0,7	1,70		Algorithm converged.	0,62	4,70	0,005		Algorithm converged.	-0,004	0,013	1,69		Algorithm converged.	0,62	4,64	0,3060		0,59		Algorithm converged.	0,22	1,62
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	3	0,5	2,44		Algorithm converged.	0,63	9,48	0,007		Algorithm converged.	-0,003	0,018	2,42		Algorithm converged.	0,63	9,32	0,1984		0,41		Algorithm converged.	0,11	1,59
	RECTAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	RENAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	1	0,4	5,31		Algorithm converged.	0,62	45,80	0,016		Algorithm converged.	-0,003	0,034		5,23		Algorithm converged.	0,62	44,48	0,1297		0,19		Algorithm converged.	0,02	1,63	
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	12	1,3	1,19		Algorithm converged.	0,55	2,58	0,002		Algorithm converged.	-0,009	0,014		1,18		Algorithm converged.	0,55	2,55	0,6638		0,84		Algorithm converged.	0,39	1,81	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013		1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41
	RESPIRATORY TRACT INFECTION VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023		3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	5	0,6	0,61		Algorithm converged.	0,14	2,55	-0,002		Algorithm converged.	-0,008	0,004		0,61		Algorithm converged.	0,15	2,54	0,4968		1,64		Algorithm converged.	0,39	6,85
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	7	1,2	0,44		Algorithm converged.	0,11	1,72	-0,006		Algorithm converged.	-0,017	0,004		0,44		Algorithm converged.	0,12	1,71	0,2387		2,25		Algorithm converged.	0,58	8,65
	RHINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	3	7,1	0,81		Algorithm converged.	0,16	4,25	-0,013		Algorithm converged.	-0,114	0,089		0,82		Algorithm converged.	0,18	3,87	0,8057	-	1,21		Algorithm converged.	0,26	5,71
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	8	3,0	0,78		Algorithm converged.	0,27	2,28	-0,006		Algorithm converged.	-0,034	0,021		0,78		Algorithm converged.	0,28	2,23	0,6493		1,27		Algorithm converged.	0,45	3,62
		1-3 positive nodes	891	50,0	64	7,2	905	49,7	40	4,4	1,67		Algorithm converged.	1,11	2,51	0,028		Algorithm converged.	0,006	0,049		1,63		Algorithm converged.	1,11	2,39	0,0132		0,62		Algorithm converged.	0,42	0,90
		>= 4 positive nodes	582	32,6	32	5,5	604	33,2	30	5,0	1,11		Algorithm converged.	0,67	1,86	0,005		Algorithm converged.	-0,020	0,031		1,11		Algorithm converged.	0,68	1,80	0,6812		0,90		Algorithm converged.	0,56	1,47
	RHINOVIRUS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SALPINGO-OOPHORITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEBACEOUS GLAND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004	0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37
	SEPTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114	2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	12	4,4	0,42		Algorithm converged.	0,15	1,22	-0,025		Algorithm converged.	-0,055	0,005	0,44		Algorithm converged.	0,16	1,22	0,1139		2,29		Algorithm converged.	0,82	6,42
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	28	3,1	0,83		Algorithm converged.	0,47	1,45	-0,005		Algorithm converged.	-0,020	0,010	0,83		Algorithm converged.	0,48	1,44	0,5138		1,20		Algorithm converged.	0,70	2,06
		>= 4 positive nodes	582	32,6	15	2,6	604	33,2	10	1,7	1,57		Algorithm converged.	0,70	3,53	0,009		Algorithm converged.	-0,007	0,026	1,56		Algorithm converged.	0,71	3,44	0,2734		0,64		Algorithm converged.	0,29	1,42
	SINUSITIS BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN CANDIDA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	5	1,8	1,26		Algorithm converged.	0,38	4,19	0,005		Algorithm converged.	-0,020	0,029		1,26		Algorithm converged.	0,39	4,06	0,7041		0,80		Algorithm converged.	0,25	2,58
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	17	1,9	1,02		Algorithm converged.	0,52	2,00	0,000		Algorithm converged.	-0,012	0,013		1,02		Algorithm converged.	0,52	1,98	0,9634		0,98		Algorithm converged.	0,51	1,92
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	8	1,3	2,11		Algorithm converged.	0,89	4,96	0,014		Algorithm converged.	-0,002	0,030		2,08		Algorithm converged.	0,90	4,81	0,0888		0,48		Algorithm converged.	0,21	1,12
	SOFT TISSUE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 45.078386058 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	STAPHYLOCOCCAL SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 45.078386058 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STREPTOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STREPTOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRONGYLOIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCUTANEOUS ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TINEA CAPITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TINEA CRURIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TINEA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	TINEA PEDIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	TONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	10	1,1	0,30		Algorithm converged.	0,08	1,10	-0,008		Algorithm converged.	-0,015	0,000	0,30		Algorithm converged.	0,08	1,10	0,0703		3,28		Algorithm converged.	0,91	11,88
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	TOOTH ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011		1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005		0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	TOOTH INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	7	0,8	1,02		Algorithm converged.	0,35	2,91	0,000		Algorithm converged.	-0,008	0,008		1,02		Algorithm converged.	0,36	2,88	0,9766		0,98		Algorithm converged.	0,35	2,80
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	6	1,0	0,69		Algorithm converged.	0,19	2,46	-0,003		Algorithm converged.	-0,013	0,007		0,69		Algorithm converged.	0,20	2,44	0,5667		1,45		Algorithm converged.	0,41	5,10

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRACHEITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	5	0,6	1,02		Algorithm converged.	0,29	3,52	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,30	3,50	0,9803		0,98		Algorithm converged.	0,29	3,39
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	TRACHEOBRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRICHOPHYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	2	4,8	1,25		Algorithm converged.	0,20	7,85	0,011		Algorithm converged.	-0,080	0,102	1,24		Algorithm converged.	0,22	7,05	0,8121	-	0,81		Algorithm converged.	0,14	4,62
		0 positive nodes, tumor > 1 cm	259	14,5	20	7,7	271	14,9	27	10,0	0,76		Algorithm converged.	0,41	1,39	-0,022		Algorithm converged.	-0,071	0,026	0,78		Algorithm converged.	0,45	1,35	0,3661		1,29		Algorithm converged.	0,74	2,24
		1-3 positive nodes	891	50,0	69	7,7	905	49,7	57	6,3	1,25		Algorithm converged.	0,87	1,80	0,014		Algorithm converged.	-0,009	0,038	1,23		Algorithm converged.	0,88	1,72	0,2314		0,81		Algorithm converged.	0,58	1,14
		>= 4 positive nodes	582	32,6	47	8,1	604	33,2	50	8,3	0,97		Algorithm converged.	0,64	1,47	-0,002		Algorithm converged.	-0,033	0,029	0,98		Algorithm converged.	0,67	1,43	0,8988		1,03		Algorithm converged.	0,70	1,50
	URETHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	5	11,9	0,46		Algorithm converged.	0,10	2,06	-0,060		Algorithm converged.	-0,178	0,057		0,49		Algorithm converged.	0,13	1,95	0,3138	-	2,02		Algorithm converged.	0,51	7,98
		0 positive nodes, tumor > 1 cm	259	14,5	21	8,1	271	14,9	22	8,1	1,00		Algorithm converged.	0,54	1,86	0,000		Algorithm converged.	-0,047	0,046		1,00		Algorithm converged.	0,56	1,77	0,9966		1,00		Algorithm converged.	0,56	1,78
		1-3 positive nodes	891	50,0	70	7,9	905	49,7	59	6,5	1,22		Algorithm converged.	0,85	1,75	0,013		Algorithm converged.	-0,011	0,037		1,21		Algorithm converged.	0,86	1,68	0,2734		0,83		Algorithm converged.	0,59	1,16
		>= 4 positive nodes	582	32,6	45	7,7	604	33,2	40	6,6	1,18		Algorithm converged.	0,76	1,84	0,011		Algorithm converged.	-0,018	0,040		1,17		Algorithm converged.	0,77	1,76	0,4595		0,86		Algorithm converged.	0,57	1,29
	URINARY TRACT INFECTION ENTEROCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URINARY TRACT INFECTION STAPHYLOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.87480164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	7	0,8	1,60		Algorithm converged.	0,62	4,16	0,005		Algorithm converged.	-0,005	0,014	1,60		Algorithm converged.	0,62	4,10	0,3312		0,63		Algorithm converged.	0,24	1,61
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	16	2,6	0,45		Algorithm converged.	0,18	1,10	-0,014		Algorithm converged.	-0,030	0,001	0,45		Algorithm converged.	0,19	1,10	0,0789		2,20		Algorithm converged.	0,91	5,31
	VAGINITIS GARDNERELLA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	VARICELLA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VARICELLA ZOSTER VIRUS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7	0,51		Algorithm converged.	0,13	2,03	-0,003		Algorithm converged.	-0,010	0,003	0,51		Algorithm converged.	0,13	2,02	0,3369		1,97		Algorithm converged.	0,49	7,85
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VESTIBULAR NEURONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	VESTIBULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133992 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8	1,16		Algorithm converged.	0,42	3,22	0,001		Algorithm converged.	-0,007	0,010	1,16		Algorithm converged.	0,42	3,19	0,7723		0,86		Algorithm converged.	0,31	2,37
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	6	1,0	1,04		Algorithm converged.	0,33	3,24	0,000		Algorithm converged.	-0,011	0,012	1,04		Algorithm converged.	0,34	3,20	0,9485		0,96		Algorithm converged.	0,31	2,97
	VIRAL PHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VIRAL RHINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VIRAL SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL TRACHEITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIRAL UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	4	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	3	0,3	3,07		Algorithm converged.	0,83	11,37	0,007		Algorithm converged.	-0,001	0,014		3,05		Algorithm converged.	0,83	11,22	0,0938		0,33		Algorithm converged.	0,09	1,21
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	2	0,3	3,66		Algorithm converged.	0,76	17,71	0,009		Algorithm converged.	-0,001	0,019		3,63		Algorithm converged.	0,76	17,41	0,1067		0,28		Algorithm converged.	0,06	1,32
	VULVOVAGINAL MYCOTIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	5	0,6	2,87		Algorithm converged.	1,03	8,01	0,010		Algorithm converged.	0,001	0,020		2,84		Algorithm converged.	1,03	7,86	0,0440		0,35		Algorithm converged.	0,13	0,97
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	5	0,8	1,46		Algorithm converged.	0,46	4,62	0,004		Algorithm converged.	-0,008	0,015		1,45		Algorithm converged.	0,46	4,55	0,5214		0,69		Algorithm converged.	0,22	2,16
	VULVOVAGINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	WOUND ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011		1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013		1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41
	WOUND INFECTION STAPHYLOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	13	25,5	42	2,3	10	23,8	1,09		Algorithm converged.	0,42	2,83	0,017		Algorithm converged.	-0,159	0,193		1,07		Algorithm converged.	0,52	2,19	0,8519	0,2980	0,93		Algorithm converged.	0,46	1,91
		0 positive nodes, tumor > 1 cm	259	14,5	69	26,6	271	14,9	50	18,5	1,61		Algorithm converged.	1,06	2,42	0,082		Algorithm converged.	0,011	0,153		1,44		Algorithm converged.	1,05	1,99	0,0252		0,69		Algorithm converged.	0,50	0,96
		1-3 positive nodes	891	50,0	236	26,5	905	49,7	233	25,7	1,04		Algorithm converged.	0,84	1,28	0,007		Algorithm converged.	-0,033	0,048		1,03		Algorithm converged.	0,88	1,20	0,7207		0,97		Algorithm converged.	0,83	1,14
		>= 4 positive nodes	582	32,6	156	26,8	604	33,2	155	25,7	1,06		Algorithm converged.	0,82	1,37	0,011		Algorithm converged.	-0,039	0,062		1,04		Algorithm converged.	0,86	1,26	0,6549		0,96		Algorithm converged.	0,79	1,16
	ACCIDENTAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ANAL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANIMAL BITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANIMAL SCRATCH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANKLE FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARTHROPOD BITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	ARTHROPOD STING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AVULSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY WEB SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PROCEDURAL COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURN ORAL CAVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURNS SECOND DEGREE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL BURN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL BURNS OF EYE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEMICAL PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHILLBLAINS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONCUSSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	CONTUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	4	1,5	1,31		Algorithm converged.	0,35	4,95	0,005		Algorithm converged.	-0,018	0,027		1,31		Algorithm converged.	0,36	4,82	0,6865			0,76		Algorithm converged.	0,21	2,82						
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	9	1,0	1,13		Algorithm converged.	0,46	2,79	0,001		Algorithm converged.	-0,008	0,011		1,13		Algorithm converged.	0,46	2,76	0,7913			0,89		Algorithm converged.	0,36	2,17						
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	4	0,7	1,30		Algorithm converged.	0,35	4,86	0,002		Algorithm converged.	-0,008	0,012		1,30		Algorithm converged.	0,35	4,81	0,6970			0,77		Algorithm converged.	0,21	2,86						
	DENTAL RESTORATION FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EPICONDYLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ESCHAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE CONTUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FACIAL BONES FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FALL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	10	1,1	0,71		Algorithm converged.	0,27	1,87	-0,003		Algorithm converged.	-0,012	0,006		0,71		Algorithm converged.	0,27	1,86	0,4869		1,41		Algorithm converged.	0,54	3,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008		1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	FEMORAL NECK FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FOOT FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008		4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	FOREIGN BODY IN THROAT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE				NE		Algorithm converged.	NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999				>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FRACTURED SACRUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GINGIVAL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HAND FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625			0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HUMERUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	ILIUM FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	INCISION SITE COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCISION SITE INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INCISION SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	6	0,7	0,68		Algorithm converged.	0,19	2,40	-0,002		Algorithm converged.	-0,009	0,005		0,68		Algorithm converged.	0,19	2,39	0,5448		1,48		Algorithm converged.	0,42	5,22
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	4	0,7	1,30		Algorithm converged.	0,35	4,86	0,002		Algorithm converged.	-0,008	0,012		1,30		Algorithm converged.	0,35	4,81	0,6970		0,77		Algorithm converged.	0,21	2,86
	INFUSION RELATED REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048		0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	12	4,6	271	14,9	13	4,8	0,96		Algorithm converged.	0,43	2,15	-0,002		Algorithm converged.	-0,038	0,034		0,97		Algorithm converged.	0,45	2,08	0,9291		1,04		Algorithm converged.	0,48	2,23
		1-3 positive nodes	891	50,0	37	4,2	905	49,7	29	3,2	1,31		Algorithm converged.	0,80	2,15	0,009		Algorithm converged.	-0,008	0,027		1,30		Algorithm converged.	0,80	2,09	0,2871		0,77		Algorithm converged.	0,48	1,24
		>= 4 positive nodes	582	32,6	20	3,4	604	33,2	19	3,1	1,10		Algorithm converged.	0,58	2,07	0,003		Algorithm converged.	-0,017	0,023		1,09		Algorithm converged.	0,59	2,03	0,7790		0,92		Algorithm converged.	0,49	1,70
	INTENTIONAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	JOINT INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002	0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LIGAMENT SPRAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	7	0,8	0,14		Algorithm converged.	0,02	1,17	-0,007		Algorithm converged.	-0,013	0,000		0,15		Algorithm converged.	0,02	1,18	0,0707		6,89		Algorithm converged.	0,85	55,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	2	0,3	2,08		Algorithm converged.	0,38	11,42	0,004		Algorithm converged.	-0,005	0,012	2,08		Algorithm converged.	0,38	11,29	0,3980		0,48		Algorithm converged.	0,09	2,62
	LIMB INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	6	0,7	0,17		Algorithm converged.	0,02	1,40	-0,006		Algorithm converged.	-0,011	0,000	0,17		Algorithm converged.	0,02	1,40	0,0998		5,91		Algorithm converged.	0,71	48,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER LIMB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE RUPTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE STRAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PELVIC FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POISONING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	POST PROCEDURAL HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE				NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	POSTMASTECTOMY LYMPHOEDEMA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PROCEDURAL DIZZINESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,003		Algorithm converged.	-0,010	0,004		0,58		Algorithm converged.	0,17	1,98	0,3841		1,72		Algorithm converged.	0,51	5,87
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010		1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY RADIATION INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	RADIATION ASSOCIATED PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-		0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029		1,74		Algorithm converged.	0,42	7,22	0,4431			0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	22	2,4	1,06		Algorithm converged.	0,59	1,92	0,002		Algorithm converged.	-0,013	0,016		1,06		Algorithm converged.	0,60	1,89	0,8384			0,94		Algorithm converged.	0,53	1,68
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	15	2,5	0,90		Algorithm converged.	0,42	1,90	-0,002		Algorithm converged.	-0,020	0,015		0,90		Algorithm converged.	0,43	1,87	0,7771			1,11		Algorithm converged.	0,53	2,32
	RADIATION NECROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION OESOPHAGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIATION PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RADIATION SKIN INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	5	11,9	0,99		Algorithm converged.	0,28	3,49	-0,001		Algorithm converged.	-0,133	0,131	0,99		Algorithm converged.	0,32	3,01	0,9834	0,4456	1,01		Algorithm converged.	0,33	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	29	11,2	271	14,9	16	5,9	2,01		Algorithm converged.	1,06	3,80	0,053		Algorithm converged.	0,005	0,100	1,90		Algorithm converged.	1,06	3,41	0,0323		0,53		Algorithm converged.	0,29	0,95
		1-3 positive nodes	891	50,0	118	13,2	905	49,7	100	11,0	1,23		Algorithm converged.	0,92	1,63	0,022		Algorithm converged.	-0,008	0,052	1,20		Algorithm converged.	0,93	1,54	0,1554		0,83		Algorithm converged.	0,65	1,07
		>= 4 positive nodes	582	32,6	91	15,6	604	33,2	83	13,7	1,16		Algorithm converged.	0,84	1,61	0,019		Algorithm converged.	-0,021	0,059	1,14		Algorithm converged.	0,86	1,50	0,3572		0,88		Algorithm converged.	0,67	1,16
	RADIUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	RIB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ROAD TRAFFIC ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	SCAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	5	0,6	1,02		Algorithm converged.	0,29	3,52	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,30	3,50	0,9803		0,98		Algorithm converged.	0,29	3,39
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005	0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	SKIN ABRASION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48
	SKIN INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN LACERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860			1,45		Algorithm converged.	0,24	8,62
	SPINAL COMPRESSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	STRESS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TENDON INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TENDON RUPTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THERMAL BURN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	9	1,0	0,79		Algorithm converged.	0,29	2,13	-0,002		Algorithm converged.	-0,011	0,007	0,79		Algorithm converged.	0,30	2,11	0,6385		1,27		Algorithm converged.	0,47	3,38
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	THORACIC VERTEBRAL FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TIBIA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	TOXICITY TO VARIOUS AGENTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRANSFUSION REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TRAUMATIC HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ULNA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER LIMB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VIITH NERVE INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VULVOVAGINAL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003	0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	WOUND COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	WOUND DEHISCENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND SECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	25	49,0	42	2,3	13	31,0	2,14		Algorithm converged.	0,91	5,04	0,181		Algorithm converged.	-0,015	0,377	1,58		Algorithm converged.	0,93	2,69	0,0899	0,0408	0,63		Algorithm converged.	0,37	1,07
		0 positive nodes, tumor > 1 cm	259	14,5	115	44,4	271	14,9	104	38,4	1,28		Algorithm converged.	0,91	1,81	0,060		Algorithm converged.	-0,023	0,144	1,16		Algorithm converged.	0,94	1,42	0,1598		0,86		Algorithm converged.	0,71	1,06
		1-3 positive nodes	891	50,0	370	41,5	905	49,7	406	44,9	0,87		Algorithm converged.	0,72	1,05	-0,033		Algorithm converged.	-0,079	0,012	0,93		Algorithm converged.	0,83	1,03	0,1541		1,08		Algorithm converged.	0,97	1,20
		>= 4 positive nodes	582	32,6	245	42,1	604	33,2	281	46,5	0,84		Algorithm converged.	0,66	1,05	-0,044		Algorithm converged.	-0,101	0,012	0,90		Algorithm converged.	0,80	1,03	0,1258		1,11		Algorithm converged.	0,97	1,26
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 42.42671629 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	3	7,1	2,42		Algorithm converged.	0,60	9,77	0,085		Algorithm converged.	-0,041	0,212		2,20		Algorithm converged.	0,62	7,76	0,2220	0,1662	0,46		Algorithm converged.	0,13	1,61
		0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	24	8,9	1,25		Algorithm converged.	0,70	2,21	0,020		Algorithm converged.	-0,031	0,070		1,22		Algorithm converged.	0,73	2,05	0,4504		0,82		Algorithm converged.	0,49	1,38
		1-3 positive nodes	891	50,0	83	9,3	905	49,7	89	9,8	0,94		Algorithm converged.	0,69	1,29	-0,005		Algorithm converged.	-0,032	0,022		0,95		Algorithm converged.	0,71	1,26	0,7087		1,06		Algorithm converged.	0,79	1,40

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	57	9,8	604	33,2	80	13,2	0,71		Algorithm converged.	0,50	1,02	-0,035		Algorithm converged.	-0,071	0,002		0,74		Algorithm converged.	0,54	1,02	0,0645		1,35		Algorithm converged.	0,98	1,86
	ASPARTATE AMINOTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ASPARTATE AMINOTRANSFERASE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	1	2,4	5,47		Algorithm converged.	0,63	47,35	0,094		Algorithm converged.	-0,006	0,194		4,94		Algorithm converged.	0,62	39,44	0,1317	-	0,20		Algorithm converged.	0,03	1,62
		0 positive nodes, tumor > 1 cm	259	14,5	18	6,9	271	14,9	16	5,9	1,19		Algorithm converged.	0,59	2,39	0,010		Algorithm converged.	-0,031	0,052		1,18		Algorithm converged.	0,61	2,26	0,6237		0,85		Algorithm converged.	0,44	1,63
		1-3 positive nodes	891	50,0	57	6,4	905	49,7	57	6,3	1,02		Algorithm converged.	0,70	1,49	0,001		Algorithm converged.	-0,022	0,024		1,02		Algorithm converged.	0,71	1,45	0,9315		0,98		Algorithm converged.	0,69	1,40
		>= 4 positive nodes	582	32,6	38	6,5	604	33,2	56	9,3	0,68		Algorithm converged.	0,45	1,05	-0,027		Algorithm converged.	-0,058	0,003		0,70		Algorithm converged.	0,47	1,05	0,0826		1,42		Algorithm converged.	0,96	2,11
	BILIRUBIN CONJUGATED INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BLOOD ALKALINE PHOSPHATASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	BLOOD ALKALINE PHOSPHATASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075		0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	16	1,8	1,08		Algorithm converged.	0,54	2,15	0,001		Algorithm converged.	-0,011	0,014		1,08		Algorithm converged.	0,55	2,12	0,8252		0,93		Algorithm converged.	0,47	1,82
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	19	3,1	0,54		Algorithm converged.	0,25	1,17	-0,014		Algorithm converged.	-0,032	0,003		0,55		Algorithm converged.	0,26	1,16	0,1175		1,83		Algorithm converged.	0,86	3,90
	BLOOD BILIRUBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BLOOD BILIRUBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	4	0,4	2,30		Algorithm converged.	0,71	7,49	0,006		Algorithm converged.	-0,002	0,014	2,29		Algorithm converged.	0,71	7,39	0,1677		0,44		Algorithm converged.	0,14	1,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001	0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN UNCONJUGATED INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CALCIUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CALCIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CHLORIDE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	5	0,6	1,22		Algorithm converged.	0,37	4,01	0,001		Algorithm converged.	-0,006	0,008	1,22		Algorithm converged.	0,37	3,98	0,7430		0,82		Algorithm converged.	0,25	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	6	1,0	0,17		Algorithm converged.	0,02	1,43	-0,008		Algorithm converged.	-0,017	0,000	0,17		Algorithm converged.	0,02	1,43	0,1038		5,78		Algorithm converged.	0,70	47,88
	BLOOD CREATINE PHOSPHOKINASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637			0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	5	0,6	1,84		Algorithm converged.	0,61	5,50	0,005		Algorithm converged.	-0,004	0,013		1,83		Algorithm converged.	0,62	5,43	0,2776			0,55		Algorithm converged.	0,18	1,63
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704			0,96		Algorithm converged.	0,14	6,82
	BLOOD GLUCOSE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE FLUCTUATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	BLOOD LACTATE DEHYDROGENASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD LACTATE DEHYDROGENASE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	8	0,9	1,92		Algorithm converged.	0,81	4,55	0,008		Algorithm converged.	-0,002	0,018	1,90		Algorithm converged.	0,81	4,47	0,1389		0,53		Algorithm converged.	0,22	1,23
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	8	1,3	0,91		Algorithm converged.	0,33	2,52	-0,001		Algorithm converged.	-0,014	0,011	0,91		Algorithm converged.	0,33	2,49	0,8513		1,10		Algorithm converged.	0,40	3,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BLOOD MAGNESIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	3	0,3	2,38		Algorithm converged.	0,61	9,24	0,005		Algorithm converged.	-0,002	0,011		2,37		Algorithm converged.	0,61	9,14	0,2101		0,42		Algorithm converged.	0,11	1,63	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001		0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11	
	BLOOD MAGNESIUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PHOSPHORUS DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BLOOD PHOSPHORUS INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02						
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37						
	BLOOD POTASSIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 42.426716291 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	BLOOD POTASSIUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DIASTOLIC DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DIASTOLIC INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BLOOD PRESSURE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	BLOOD SODIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD SODIUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD UREA DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD UREA INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003	0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BLOOD URIC ACID INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD URINE PRESENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BODY TEMPERATURE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREATH SOUNDS ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	C-REACTIVE PROTEIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	CARBOHYDRATE ANTIGEN 125 INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARBOHYDRATE ANTIGEN 15-3 INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CARDIAC MURMUR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM TEST POSITIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CREATININE RENAL CLEARANCE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DELTARETROVIRUS TEST POSITIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ECHOCARDIOGRAM ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	12	4,4	1,14		Algorithm converged.	0,51	2,55	0,006		Algorithm converged.	-0,030	0,042		1,13		Algorithm converged.	0,53	2,44	0,7484		0,88		Algorithm converged.	0,41	1,90
		1-3 positive nodes	891	50,0	48	5,4	905	49,7	64	7,1	0,75		Algorithm converged.	0,51	1,10	-0,017		Algorithm converged.	-0,039	0,005		0,76		Algorithm converged.	0,53	1,09	0,1414		1,31		Algorithm converged.	0,91	1,89
		>= 4 positive nodes	582	32,6	24	4,1	604	33,2	35	5,8	0,70		Algorithm converged.	0,41	1,19	-0,017		Algorithm converged.	-0,041	0,008		0,71		Algorithm converged.	0,43	1,18	0,1883		1,41		Algorithm converged.	0,85	2,33
	ELECTROCARDIOGRAM ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM QT PROLONGED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ELECTROCARDIOGRAM ST-T CHANGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ELECTROCARDIOGRAM T WAVE ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROCARDIOGRAM T WAVE INVERSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EOSINOPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	EOSINOPHIL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FORCED EXPIRATORY VOLUME DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GAMMA-GLUTAMYLTRANSFERASE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	18	2,0	0,28		Algorithm converged.	0,10	0,75	-0,014		Algorithm converged.	-0,025	-0,004	0,28		Algorithm converged.	0,11	0,76	0,0119		3,54		Algorithm converged.	1,32	9,51
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	13	2,2	0,71		Algorithm converged.	0,30	1,68	-0,006		Algorithm converged.	-0,021	0,009	0,72		Algorithm converged.	0,31	1,67	0,4417		1,39		Algorithm converged.	0,60	3,23
	GLOMERULAR FILTRATION RATE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLYCOSYLATED HAEMOGLOBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMATOCRIT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMOGLOBIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HAEMOGLOBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114	2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2	0,52		Algorithm converged.	0,13	2,09	-0,011		Algorithm converged.	-0,032	0,011	0,52		Algorithm converged.	0,13	2,07	0,3559		1,91		Algorithm converged.	0,48	7,56
		1-3 positive nodes	891	50,0	27	3,0	905	49,7	33	3,6	0,83		Algorithm converged.	0,49	1,39	-0,006		Algorithm converged.	-0,023	0,010	0,83		Algorithm converged.	0,50	1,37	0,4683		1,20		Algorithm converged.	0,73	1,98
		>= 4 positive nodes	582	32,6	22	3,8	604	33,2	19	3,1	1,21		Algorithm converged.	0,65	2,26	0,006		Algorithm converged.	-0,014	0,027	1,20		Algorithm converged.	0,66	2,20	0,5506		0,83		Algorithm converged.	0,46	1,52
	HAEMOGLOBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAPTOGLOBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEART RATE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	HELICOBACTER TEST POSITIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC ENZYME ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC ENZYME INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HUMAN CHORIONIC GONADOTROPIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	LIPASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTE COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	5	0,8	1,46		Algorithm converged.	0,46	4,62	0,004		Algorithm converged.	-0,008	0,015	1,45		Algorithm converged.	0,46	4,55	0,5214		0,69		Algorithm converged.	0,22	2,16
	LYMPHOCYTE COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	MEGAKARYOCYTES ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	METAMYELOCYTE COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONONUCLEAR CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	9	17,6	42	2,3	6	14,3	1,29		Algorithm converged.	0,42	3,96	0,034		Algorithm converged.	-0,115	0,182	1,24		Algorithm converged.	0,48	3,19	0,6625	0,7663	0,81		Algorithm converged.	0,31	2,09
		0 positive nodes, tumor > 1 cm	259	14,5	42	16,2	271	14,9	43	15,9	1,03		Algorithm converged.	0,65	1,63	0,003		Algorithm converged.	-0,059	0,066	1,02		Algorithm converged.	0,69	1,51	0,9128		0,98		Algorithm converged.	0,66	1,44
		1-3 positive nodes	891	50,0	118	13,2	905	49,7	129	14,3	0,92		Algorithm converged.	0,70	1,20	-0,010		Algorithm converged.	-0,042	0,022	0,93		Algorithm converged.	0,74	1,17	0,5343		1,08		Algorithm converged.	0,85	1,36
		>= 4 positive nodes	582	32,6	93	16,0	604	33,2	87	14,4	1,13		Algorithm converged.	0,82	1,55	0,016		Algorithm converged.	-0,025	0,057	1,11		Algorithm converged.	0,85	1,45	0,4499		0,90		Algorithm converged.	0,69	1,18
	NEUTROPHIL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHYSICAL EXAMINATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHYSICAL EXAMINATION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	11	4,2	271	14,9	11	4,1	1,05		Algorithm converged.	0,45	2,46	0,002		Algorithm converged.	-0,032	0,036		1,05		Algorithm converged.	0,46	2,37	0,9136		0,96		Algorithm converged.	0,42	2,17
		1-3 positive nodes	891	50,0	29	3,3	905	49,7	35	3,9	0,84		Algorithm converged.	0,51	1,38	-0,006		Algorithm converged.	-0,023	0,011		0,84		Algorithm converged.	0,52	1,36	0,4844		1,19		Algorithm converged.	0,73	1,93
		>= 4 positive nodes	582	32,6	21	3,6	604	33,2	18	3,0	1,22		Algorithm converged.	0,64	2,31	0,006		Algorithm converged.	-0,014	0,027		1,21		Algorithm converged.	0,65	2,25	0,5449		0,83		Algorithm converged.	0,44	1,53
	PLATELET COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009		1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008		1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROTEIN TOTAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROTEIN TOTAL DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROTEIN URINE PRESENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RED BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	8	0,9	0,89		Algorithm converged.	0,32	2,46	-0,001		Algorithm converged.	-0,009	0,007	0,89		Algorithm converged.	0,32	2,44	0,8190		1,13		Algorithm converged.	0,41	3,09
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	2	0,3	4,20		Algorithm converged.	0,89	19,84	0,010		Algorithm converged.	0,000	0,021	4,15		Algorithm converged.	0,89	19,47	0,0710		0,24		Algorithm converged.	0,05	1,13
	SERUM FERRITIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMEAR CERVIX ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID FUNCTION TEST ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THYROID FUNCTION TEST NORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TRANSAMINASES DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSAMINASES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	11	1,2	0,46		Algorithm converged.	0,16	1,33	-0,007		Algorithm converged.	-0,015	0,002	0,46		Algorithm converged.	0,16	1,32	0,1503		2,17		Algorithm converged.	0,76	6,21
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	6	1,0	1,92		Algorithm converged.	0,71	5,23	0,009		Algorithm converged.	-0,005	0,023	1,90		Algorithm converged.	0,71	5,11	0,2020		0,53		Algorithm converged.	0,20	1,41
	TRANSFERRIN SATURATION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN T INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINE ANALYSIS ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINE OUTPUT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VITAMIN B12 DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITAMIN D DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WEIGHT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	30	11,6	271	14,9	6	2,2	5,79		Algorithm converged.	2,37	14,15	0,094		Algorithm converged.	0,051	0,136	5,23		Algorithm converged.	2,21	12,36	0,0002		0,19		Algorithm converged.	0,08	0,45
		1-3 positive nodes	891	50,0	70	7,9	905	49,7	37	4,1	2,00		Algorithm converged.	1,33	3,01	0,038		Algorithm converged.	0,016	0,060	1,92		Algorithm converged.	1,30	2,83	0,0010		0,52		Algorithm converged.	0,35	0,77
		>= 4 positive nodes	582	32,6	38	6,5	604	33,2	22	3,6	1,85		Algorithm converged.	1,08	3,16	0,029		Algorithm converged.	0,004	0,054	1,79		Algorithm converged.	1,07	2,99	0,0256		0,56		Algorithm converged.	0,33	0,93
	WEIGHT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	10	3,7	0,83		Algorithm converged.	0,32	2,14	-0,006		Algorithm converged.	-0,037	0,025	0,84		Algorithm converged.	0,34	2,09	0,7029		1,19		Algorithm converged.	0,48	2,98
		1-3 positive nodes	891	50,0	25	2,8	905	49,7	56	6,2	0,44		Algorithm converged.	0,27	0,71	-0,034		Algorithm converged.	-0,053	-0,015	0,45		Algorithm converged.	0,29	0,72	0,0008		2,21		Algorithm converged.	1,39	3,50
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	37	6,1	0,32		Algorithm converged.	0,17	0,63	-0,041		Algorithm converged.	-0,063	-0,018	0,34		Algorithm converged.	0,18	0,64	0,0009		2,97		Algorithm converged.	1,56	5,64
	WHITE BLOOD CELL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	1	2,4	4,46		Algorithm converged.	0,50	39,74	0,074		Algorithm converged.	-0,020	0,168	4,12		Algorithm converged.	0,50	33,89	0,1882	-	0,24		Algorithm converged.	0,03	2,00
		0 positive nodes, tumor > 1 cm	259	14,5	19	7,3	271	14,9	20	7,4	0,99		Algorithm converged.	0,52	1,91	0,000		Algorithm converged.	-0,045	0,044	0,99		Algorithm converged.	0,54	1,82	0,9845		1,01		Algorithm converged.	0,55	1,84
		1-3 positive nodes	891	50,0	96	10,8	905	49,7	87	9,6	1,14		Algorithm converged.	0,84	1,54	0,012		Algorithm converged.	-0,016	0,040	1,12		Algorithm converged.	0,85	1,48	0,4163		0,89		Algorithm converged.	0,68	1,17
		>= 4 positive nodes	582	32,6	83	14,3	604	33,2	61	10,1	1,48		Algorithm converged.	1,04	2,11	0,042		Algorithm converged.	0,004	0,079	1,41		Algorithm converged.	1,04	1,93	0,0293		0,71		Algorithm converged.	0,52	0,97
	WHITE BLOOD CELL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 37.991816656 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,092		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	16	31,4	42	2,3	14	33,3	0,91		Algorithm converged.	0,38	2,19	-0,020		Algorithm converged.	-0,211	0,172	0,94		Algorithm converged.	0,52	1,70	0,8403	0,6446	1,06		Algorithm converged.	0,59	1,92
		0 positive nodes, tumor > 1 cm	259	14,5	100	38,6	271	14,9	88	32,5	1,31		Algorithm converged.	0,92	1,87	0,061		Algorithm converged.	-0,020	0,143	1,19		Algorithm converged.	0,94	1,50	0,1407		0,84		Algorithm converged.	0,67	1,06
		1-3 positive nodes	891	50,0	315	35,4	905	49,7	264	29,2	1,33		Algorithm converged.	1,09	1,62	0,062		Algorithm converged.	0,019	0,105	1,21		Algorithm converged.	1,06	1,39	0,0052		0,83		Algorithm converged.	0,72	0,94
		>= 4 positive nodes	582	32,6	202	34,7	604	33,2	194	32,1	1,12		Algorithm converged.	0,88	1,43	0,026		Algorithm converged.	-0,028	0,080	1,08		Algorithm converged.	0,92	1,27	0,3448		0,93		Algorithm converged.	0,79	1,09
	ACIDOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	APPETITE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CACHEXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELL DEATH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	DECREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	7	16,7	1,37		Algorithm converged.	0,48	3,93	0,049		Algorithm converged.	-0,110	0,209		1,29		Algorithm converged.	0,55	3,04	0,5545	0,6964		0,77		Algorithm converged.	0,33	1,82	
		0 positive nodes, tumor > 1 cm	259	14,5	67	25,9	271	14,9	62	22,9	1,18		Algorithm converged.	0,79	1,75	0,030		Algorithm converged.	-0,043	0,103		1,13		Algorithm converged.	0,84	1,53	0,4229			0,88		Algorithm converged.	0,65	1,19	
		1-3 positive nodes	891	50,0	213	23,9	905	49,7	172	19,0	1,34		Algorithm converged.	1,07	1,68	0,049		Algorithm converged.	0,011	0,087		1,26		Algorithm converged.	1,05	1,50	0,0117			0,80		Algorithm converged.	0,67	0,95	
		>= 4 positive nodes	582	32,6	136	23,4	604	33,2	132	21,9	1,09		Algorithm converged.	0,83	1,43	0,015		Algorithm converged.	-0,032	0,063		1,07		Algorithm converged.	0,87	1,32	0,5334			0,94		Algorithm converged.	0,76	1,15	
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	3	7,1	0,26		Algorithm converged.	0,03	2,60	-0,052		Algorithm converged.	-0,139	0,035		0,27		Algorithm converged.	0,03	2,54	0,2550	-		3,64		Algorithm converged.	0,39	33,74	
		0 positive nodes, tumor > 1 cm	259	14,5	9	3,5	271	14,9	6	2,2	1,59		Algorithm converged.	0,56	4,53	0,013		Algorithm converged.	-0,016	0,041		1,57		Algorithm converged.	0,57	4,35	0,3859			0,64		Algorithm converged.	0,23	1,76	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	17	1,9	2,01		Algorithm converged.	1,11	3,63	0,018		Algorithm converged.	0,003	0,033	1,97		Algorithm converged.	1,11	3,51	0,0213		0,51		Algorithm converged.	0,28	0,90
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	13	2,2	1,45		Algorithm converged.	0,70	2,99	0,009		Algorithm converged.	-0,009	0,028	1,44		Algorithm converged.	0,71	2,91	0,3130		0,70		Algorithm converged.	0,34	1,41
	DIABETES MELLITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETIC METABOLIC DECOMPENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSLIPIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ELECTROLYTE IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAILURE TO THRIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE		NE	NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE		NE	NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE		NE	NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE		NE	NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	2	0,2	7,21		Algorithm converged.	1,63	31,81	0,014		Algorithm converged.	0,005	0,022	7,11		Algorithm converged.	1,62	31,19	0,0093		0,14		Algorithm converged.	0,03	0,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	FOLATE DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	FOOD AVERSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE			
	GOUT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE					NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMOCHROMATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	6	1,0	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPERCHLORAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	HYPERCHOLESTEROLAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047	0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2	0,52		Algorithm converged.	0,13	2,09	-0,011		Algorithm converged.	-0,032	0,011	0,52		Algorithm converged.	0,13	2,07	0,3559		1,91		Algorithm converged.	0,48	7,56
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	14	1,5	0,80		Algorithm converged.	0,36	1,76	-0,003		Algorithm converged.	-0,014	0,008	0,80		Algorithm converged.	0,36	1,75	0,5729		1,25		Algorithm converged.	0,57	2,75
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	15	2,5	0,83		Algorithm converged.	0,38	1,78	-0,004		Algorithm converged.	-0,021	0,013	0,83		Algorithm converged.	0,39	1,76	0,6271		1,20		Algorithm converged.	0,57	2,55
	HYPERKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	HYPERNATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744			0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124			0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269			3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003		0,51		Algorithm converged.	0,09	2,77	0,4333			1,97		Algorithm converged.	0,36	10,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	6	1,0	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERURICAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005		0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48
	HYPOALBUMINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005		0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	10	1,1	1,95		Algorithm converged.	0,90	4,22	0,010		Algorithm converged.	-0,001	0,022		1,93		Algorithm converged.	0,90	4,13	0,0900		0,52		Algorithm converged.	0,24	1,11
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	9	1,5	1,63		Algorithm converged.	0,70	3,79	0,009		Algorithm converged.	-0,007	0,025		1,61		Algorithm converged.	0,70	3,70	0,2578		0,62		Algorithm converged.	0,27	1,42
	HYPOCHLORAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048	0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	8	3,0	2,31		Algorithm converged.	0,98	5,45	0,036		Algorithm converged.	0,000	0,072	2,22		Algorithm converged.	0,98	5,06	0,0570		0,45		Algorithm converged.	0,20	1,02
		1-3 positive nodes	891	50,0	58	6,5	905	49,7	42	4,6	1,43		Algorithm converged.	0,95	2,15	0,019		Algorithm converged.	-0,003	0,040	1,40		Algorithm converged.	0,95	2,06	0,0859		0,71		Algorithm converged.	0,48	1,05
		>= 4 positive nodes	582	32,6	31	5,3	604	33,2	27	4,5	1,20		Algorithm converged.	0,71	2,04	0,009		Algorithm converged.	-0,016	0,033	1,19		Algorithm converged.	0,72	1,97	0,4949		0,84		Algorithm converged.	0,51	1,39
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	4	9,5	0,19		Algorithm converged.	0,02	1,77	-0,076		Algorithm converged.	-0,172	0,021	0,21		Algorithm converged.	0,02	1,77	0,1502	-	4,86		Algorithm converged.	0,56	41,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	23	8,9	271	14,9	4	1,5	6,51		Algorithm converged.	2,22	19,08	0,074		Algorithm converged.	0,037	0,112	6,02		Algorithm converged.	2,11	17,16	0,0008		0,17		Algorithm converged.	0,06	0,47
		1-3 positive nodes	891	50,0	54	6,1	905	49,7	37	4,1	1,51		Algorithm converged.	0,99	2,32	0,020		Algorithm converged.	-0,001	0,040	1,48		Algorithm converged.	0,99	2,23	0,0586		0,67		Algorithm converged.	0,45	1,01
		>= 4 positive nodes	582	32,6	29	5,0	604	33,2	15	2,5	2,06		Algorithm converged.	1,09	3,88	0,025		Algorithm converged.	0,003	0,047	2,01		Algorithm converged.	1,09	3,70	0,0260		0,50		Algorithm converged.	0,27	0,92
	HYPONATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	4	9,5	0,00		Algorithm converged.	0,00	NE	-0,115	*	WARNING: The relative Hessian convergence criterion of 3.8507836774 is greater than the limit of 0.0001. The convergence is questionable.	-0,409	0,179	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	5	1,8	0,41		Algorithm converged.	0,08	2,15	-0,011		Algorithm converged.	-0,030	0,009	0,42		Algorithm converged.	0,08	2,14	0,2952		2,39		Algorithm converged.	0,47	12,21
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	7	0,8	0,87		Algorithm converged.	0,29	2,60	-0,001		Algorithm converged.	-0,009	0,007	0,87		Algorithm converged.	0,29	2,58	0,8026		1,15		Algorithm converged.	0,39	3,40
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	2	0,3	3,14		Algorithm converged.	0,63	15,60	0,007		Algorithm converged.	-0,002	0,016	3,11		Algorithm converged.	0,63	15,36	0,1632		0,32		Algorithm converged.	0,07	1,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8	1,16		Algorithm converged.	0,42	3,22	0,001		Algorithm converged.	-0,007	0,010	1,16		Algorithm converged.	0,42	3,19	0,7723		0,86		Algorithm converged.	0,31	2,37
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	HYPOPROTEINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOVOLAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	IRON DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013		4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	LACTOSE INTOLERANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
	LIPOEDEMA	0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAGNESIUM DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OBESITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POLYDIPSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TETANY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TUMOUR LYSIS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TYPE 2 DIABETES MELLITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITAMIN B12 DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VITAMIN C DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VITAMIN D DEFICIENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39									
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011	1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87									
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72									
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	29	56,9	42	2,3	23	54,8	1,09		Algorithm converged.	0,48	2,48	0,021		Algorithm converged.	-0,182	0,224	1,04		Algorithm converged.	0,72	1,49	0,8395	0,0120	0,96		Algorithm converged.	0,67	1,39									
		0 positive nodes, tumor > 1 cm	259	14,5	155	59,8	271	14,9	201	74,2	0,52		Algorithm converged.	0,36	0,75	-0,143		Algorithm converged.	-0,222	-0,064	0,81		Algorithm converged.	0,71	0,91	0,0006		1,24		Algorithm converged.	1,10	1,40									
		1-3 positive nodes	891	50,0	571	64,1	905	49,7	599	66,2	0,91		Algorithm converged.	0,75	1,11	-0,021		Algorithm converged.	-0,065	0,023	0,97		Algorithm converged.	0,90	1,04	0,3501		1,03		Algorithm converged.	0,97	1,11									
		>= 4 positive nodes	582	32,6	361	62,0	604	33,2	362	59,9	1,09		Algorithm converged.	0,86	1,38	0,021		Algorithm converged.	-0,035	0,076	1,03		Algorithm converged.	0,94	1,13	0,4599		0,97		Algorithm converged.	0,88	1,06									
	ARTHRALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	15	29,4	42	2,3	9	21,4	1,53		Algorithm converged.	0,59	3,96	0,080		Algorithm converged.	-0,096	0,256	1,37		Algorithm converged.	0,67	2,82	0,3876	0,2795	0,73		Algorithm converged.	0,36	1,49									
		0 positive nodes, tumor > 1 cm	259	14,5	79	30,5	271	14,9	97	35,8	0,79		Algorithm converged.	0,55	1,13	-0,053		Algorithm converged.	-0,133	0,027	0,85		Algorithm converged.	0,67	1,09	0,1976		1,17		Algorithm converged.	0,92	1,50									
		1-3 positive nodes	891	50,0	272	30,5	905	49,7	311	34,4	0,84		Algorithm converged.	0,69	1,02	-0,038		Algorithm converged.	-0,082	0,005	0,89		Algorithm converged.	0,78	1,02	0,0830		1,13		Algorithm converged.	0,98	1,29									
		>= 4 positive nodes	582	32,6	168	28,9	604	33,2	166	27,5	1,07		Algorithm converged.	0,83	1,38	0,014		Algorithm converged.	-0,037	0,065	1,05		Algorithm converged.	0,88	1,26	0,5967		0,95		Algorithm converged.	0,79	1,14									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	8	0,9	1,02		Algorithm converged.	0,38	2,72	0,000		Algorithm converged.	-0,009	0,009	1,02		Algorithm converged.	0,38	2,69	0,9750		0,98		Algorithm converged.	0,37	2,61
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	ARTHROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	6	14,3	0,65		Algorithm converged.	0,18	2,31	-0,045		Algorithm converged.	-0,178	0,089	0,69		Algorithm converged.	0,23	2,09	0,5079	0,4427	1,46		Algorithm converged.	0,48	4,44
		0 positive nodes, tumor > 1 cm	259	14,5	19	7,3	271	14,9	33	12,2	0,57		Algorithm converged.	0,32	1,03	-0,048		Algorithm converged.	-0,099	0,002	0,60		Algorithm converged.	0,35	1,03	0,0649		1,66		Algorithm converged.	0,97	2,84
		1-3 positive nodes	891	50,0	77	8,6	905	49,7	87	9,6	0,89		Algorithm converged.	0,64	1,23	-0,010		Algorithm converged.	-0,036	0,017	0,90		Algorithm converged.	0,67	1,20	0,4752		1,11		Algorithm converged.	0,83	1,49
		>= 4 positive nodes	582	32,6	55	9,5	604	33,2	57	9,4	1,00		Algorithm converged.	0,68	1,48	0,000		Algorithm converged.	-0,033	0,033	1,00		Algorithm converged.	0,70	1,42	0,9939		1,00		Algorithm converged.	0,70	1,42
	BONE FORMATION INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BONE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	7	16,7	0,31		Algorithm converged.	0,08	1,29	-0,108		Algorithm converged.	-0,238	0,022		0,35		Algorithm converged.	0,10	1,28	0,1134	0,1096	2,83		Algorithm converged.	0,78	10,29
		0 positive nodes, tumor > 1 cm	259	14,5	31	12,0	271	14,9	28	10,3	1,18		Algorithm converged.	0,69	2,03	0,016		Algorithm converged.	-0,037	0,070		1,16		Algorithm converged.	0,72	1,88	0,5496		0,86		Algorithm converged.	0,53	1,40
		1-3 positive nodes	891	50,0	85	9,5	905	49,7	109	12,0	0,77		Algorithm converged.	0,57	1,04	-0,025		Algorithm converged.	-0,054	0,004		0,79		Algorithm converged.	0,61	1,04	0,0884		1,26		Algorithm converged.	0,97	1,65
		>= 4 positive nodes	582	32,6	54	9,3	604	33,2	48	7,9	1,18		Algorithm converged.	0,79	1,78	0,013		Algorithm converged.	-0,019	0,045		1,17		Algorithm converged.	0,81	1,69	0,4142		0,86		Algorithm converged.	0,59	1,24
	BURSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82						
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
	CHEST WALL MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COCCYDYNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONNECTIVE TISSUE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COSTOCHONDRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	DACTYLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUPUYTREN'S CONTRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXOSTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FIBROMYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	FLANK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	6	1,0	0,34		Algorithm converged.	0,07	1,71	-0,006		Algorithm converged.	-0,016	0,003	0,35		Algorithm converged.	0,07	1,71	0,1924		2,89		Algorithm converged.	0,59	14,26
	GROIN PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMARTHROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERVERTEBRAL DISC PROTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	JAW CLICKING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	JOINT INSTABILITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	JOINT LOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT NOISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
	JOINT RANGE OF MOTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999				Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	6	0,7	0,68		Algorithm converged.	0,19	2,40	-0,002		Algorithm converged.	-0,009	0,005		0,68		Algorithm converged.	0,19	2,39	0,5448				Algorithm converged.	0,42	5,22					
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014		1,56		Algorithm converged.	0,44	5,49	0,4912				Algorithm converged.	0,18	2,26					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	JOINT STIFFNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04						
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	8	0,9	0,89		Algorithm converged.	0,32	2,46	-0,001		Algorithm converged.	-0,009	0,007	0,89		Algorithm converged.	0,32	2,44	0,8190		1,13		Algorithm converged.	0,41	3,09						
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08						
	JOINT SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	7	0,8	0,87		Algorithm converged.	0,29	2,60	-0,001		Algorithm converged.	-0,009	0,007	0,87		Algorithm converged.	0,29	2,58	0,8026		1,15		Algorithm converged.	0,39	3,40						
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62						
	LIMB DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	9	1,0	0,90		Algorithm converged.	0,35	2,35	-0,001		Algorithm converged.	-0,010	0,008	0,90		Algorithm converged.	0,35	2,33	0,8326		1,11		Algorithm converged.	0,43	2,86						
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72						
	LIMB MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE ATROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCLE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE RIGIDITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCLE SPASMS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048		0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	23	8,9	271	14,9	14	5,2	1,79		Algorithm converged.	0,90	3,56	0,037		Algorithm converged.	-0,006	0,081		1,72		Algorithm converged.	0,90	3,27	0,0983		0,58		Algorithm converged.	0,31	1,11
		1-3 positive nodes	891	50,0	91	10,2	905	49,7	36	4,0	2,75		Algorithm converged.	1,84	4,09	0,062		Algorithm converged.	0,039	0,086		2,57		Algorithm converged.	1,77	3,73	<.0001		0,39		Algorithm converged.	0,27	0,57
		>= 4 positive nodes	582	32,6	43	7,4	604	33,2	31	5,1	1,47		Algorithm converged.	0,92	2,37	0,023		Algorithm converged.	-0,005	0,050		1,44		Algorithm converged.	0,92	2,25	0,1106		0,69		Algorithm converged.	0,44	1,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCLE TIGHTNESS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCLE TWITCHING	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002	0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	1	0,2	7,34		Algorithm converged.	0,90	59,85	0,010		Algorithm converged.	0,001	0,020	7,26		Algorithm converged.	0,90	58,86	0,0632		0,14		Algorithm converged.	0,02	1,12
	MUSCULAR WEAKNESS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	4	1,5	1,85		Algorithm converged.	0,54	6,41	0,012		Algorithm converged.	-0,012	0,037	1,83		Algorithm converged.	0,54	6,18	0,3298		0,55		Algorithm converged.	0,16	1,84
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	23	2,5	0,26		Algorithm converged.	0,11	0,64	-0,019		Algorithm converged.	-0,030	-0,007	0,26		Algorithm converged.	0,11	0,65	0,0036		3,77		Algorithm converged.	1,54	9,22
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	4	0,7	2,89		Algorithm converged.	0,91	9,13	0,012		Algorithm converged.	-0,001	0,025	2,85		Algorithm converged.	0,91	8,91	0,0711		0,35		Algorithm converged.	0,11	1,09
	MUSCULOSKELETAL CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	9	3,3	0,69		Algorithm converged.	0,24	1,97	-0,010		Algorithm converged.	-0,038	0,018	0,70		Algorithm converged.	0,25	1,93	0,4884		1,43		Algorithm converged.	0,52	3,97
		1-3 positive nodes	891	50,0	27	3,0	905	49,7	30	3,3	0,91		Algorithm converged.	0,54	1,55	-0,003		Algorithm converged.	-0,019	0,013	0,91		Algorithm converged.	0,55	1,52	0,7309		1,09		Algorithm converged.	0,66	1,82
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	16	2,6	1,11		Algorithm converged.	0,55	2,21	0,003		Algorithm converged.	-0,016	0,021	1,10		Algorithm converged.	0,56	2,16	0,7760		0,91		Algorithm converged.	0,46	1,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MUSCULOSKELETAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34	
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821801 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	MUSCULOSKELETAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULOSKELETAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	2	4,8	2,67		Algorithm converged.	0,51	13,97	0,070		Algorithm converged.	-0,039	0,179		2,47		Algorithm converged.	0,53	11,61	0,2519	-	0,40		Algorithm converged.	0,09	1,90
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	16	5,9	0,84		Algorithm converged.	0,40	1,79	-0,009		Algorithm converged.	-0,048	0,030		0,85		Algorithm converged.	0,42	1,73	0,6548		1,18		Algorithm converged.	0,58	2,40
		1-3 positive nodes	891	50,0	52	5,8	905	49,7	66	7,3	0,79		Algorithm converged.	0,54	1,15	-0,015		Algorithm converged.	-0,037	0,008		0,80		Algorithm converged.	0,56	1,14	0,2140		1,25		Algorithm converged.	0,88	1,78
		>= 4 positive nodes	582	32,6	32	5,5	604	33,2	41	6,8	0,80		Algorithm converged.	0,50	1,29	-0,013		Algorithm converged.	-0,040	0,014		0,81		Algorithm converged.	0,52	1,27	0,3567		1,23		Algorithm converged.	0,79	1,93
	MUSCULOSKELETAL STIFFNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	13	4,8	0,23		Algorithm converged.	0,07	0,83	-0,036		Algorithm converged.	-0,065	-0,008	0,24		Algorithm converged.	0,07	0,84	0,0251		4,14		Algorithm converged.	1,19	14,37
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	9	1,0	1,36		Algorithm converged.	0,57	3,24	0,004		Algorithm converged.	-0,006	0,013	1,35		Algorithm converged.	0,57	3,20	0,4891		0,74		Algorithm converged.	0,31	1,74
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	11	1,8	0,37		Algorithm converged.	0,12	1,18	-0,011		Algorithm converged.	-0,024	0,001	0,38		Algorithm converged.	0,12	1,18	0,0935		2,65		Algorithm converged.	0,85	8,27
	MYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	12	23,5	42	2,3	12	28,6	0,77		Algorithm converged.	0,30	1,95	-0,050		Algorithm converged.	-0,230	0,129	0,82		Algorithm converged.	0,41	1,64	0,5802	0,2197	1,21		Algorithm converged.	0,61	2,42
		0 positive nodes, tumor > 1 cm	259	14,5	65	25,1	271	14,9	98	36,2	0,59		Algorithm converged.	0,41	0,86	-0,111		Algorithm converged.	-0,189	-0,033	0,69		Algorithm converged.	0,53	0,90	0,0065		1,44		Algorithm converged.	1,11	1,87
		1-3 positive nodes	891	50,0	236	26,5	905	49,7	255	28,2	0,92		Algorithm converged.	0,75	1,13	-0,017		Algorithm converged.	-0,058	0,024	0,94		Algorithm converged.	0,81	1,09	0,4220		1,06		Algorithm converged.	0,91	1,24
		>= 4 positive nodes	582	32,6	148	25,4	604	33,2	163	27,0	0,92		Algorithm converged.	0,71	1,20	-0,016		Algorithm converged.	-0,066	0,034	0,94		Algorithm converged.	0,78	1,14	0,5424		1,06		Algorithm converged.	0,88	1,28
	MYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NECK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	17	1,9	1,08		Algorithm converged.	0,55	2,10	0,001		Algorithm converged.	-0,011	0,014	1,08		Algorithm converged.	0,56	2,07	0,8280		0,93		Algorithm converged.	0,48	1,79
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	14	2,3	0,96		Algorithm converged.	0,45	2,07	-0,001		Algorithm converged.	-0,018	0,016	0,96		Algorithm converged.	0,46	2,03	0,9226		1,04		Algorithm converged.	0,49	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OSTEOARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918			1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	6	0,7	0,85		Algorithm converged.	0,26	2,78	-0,001		Algorithm converged.	-0,008	0,006		0,85		Algorithm converged.	0,26	2,76	0,7824			1,18		Algorithm converged.	0,36	3,86
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860			1,45		Algorithm converged.	0,24	8,62
	OSTEONECROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OSTEOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	9	1,0	1,36		Algorithm converged.	0,57	3,24	0,004		Algorithm converged.	-0,006	0,013	1,35		Algorithm converged.	0,57	3,20	0,4891		0,74		Algorithm converged.	0,31	1,74
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	4	0,7	2,09		Algorithm converged.	0,63	6,98	0,007		Algorithm converged.	-0,004	0,019	2,08		Algorithm converged.	0,63	6,86	0,2310		0,48		Algorithm converged.	0,15	1,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OSTEOPOROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,080	*	WARNING: The relative Hessian convergence criterion of 3.6622958534 is greater than the limit of 0.0001. The convergence is questionable.	-0,234	0,394	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	13	1,4	0,94		Algorithm converged.	0,43	2,06	-0,001		Algorithm converged.	-0,012	0,010	0,94		Algorithm converged.	0,43	2,04	0,8712		1,07		Algorithm converged.	0,49	2,32
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	8	1,3	1,04		Algorithm converged.	0,39	2,79	0,001		Algorithm converged.	-0,013	0,014	1,04		Algorithm converged.	0,39	2,75	0,9404		0,96		Algorithm converged.	0,36	2,55
	PAIN IN EXTREMITY	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	7	16,7	0,54		Algorithm converged.	0,16	1,86	-0,069		Algorithm converged.	-0,208	0,071	0,59		Algorithm converged.	0,20	1,72	0,3322	0,3784	1,70		Algorithm converged.	0,58	4,97
		0 positive nodes, tumor > 1 cm	259	14,5	21	8,1	271	14,9	32	11,8	0,66		Algorithm converged.	0,37	1,18	-0,037		Algorithm converged.	-0,088	0,014	0,69		Algorithm converged.	0,41	1,16	0,1592		1,46		Algorithm converged.	0,86	2,46
		1-3 positive nodes	891	50,0	107	12,0	905	49,7	104	11,5	1,05		Algorithm converged.	0,79	1,40	0,005		Algorithm converged.	-0,025	0,035	1,05		Algorithm converged.	0,81	1,35	0,7336		0,96		Algorithm converged.	0,74	1,23

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	48	8,2	604	33,2	59	9,8	0,83		Algorithm converged.	0,56	1,24	-0,015		Algorithm converged.	-0,048	0,017		0,84		Algorithm converged.	0,59	1,21	0,3616		1,18		Algorithm converged.	0,82	1,70
	PAIN IN JAW	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7	0,51		Algorithm converged.	0,13	2,03	-0,003		Algorithm converged.	-0,010	0,003		0,51		Algorithm converged.	0,13	2,02	0,3369		1,97		Algorithm converged.	0,49	7,85
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	PERIARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERIOSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PLANTAR FASCIITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PSORIATIC ARTHROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ROTATOR CUFF SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SACRAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SACROILIITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SJOGREN'S SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL OSTEOARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	SPINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011	1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	SPINAL STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNOVIAL CYST	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SYSTEMIC LUPUS ERYTHEMATOSUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TEMPOROMANDIBULAR JOINT SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TENDINOUS CONTRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TENDON DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TENDON PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TENDONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	3	0,3	2,38		Algorithm converged.	0,61	9,24	0,005		Algorithm converged.	-0,002	0,011		2,37		Algorithm converged.	0,61	9,14	0,2101		0,42		Algorithm converged.	0,11	1,63	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TENOSYNOVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625	-	0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	TENOSYNOVITIS STENOSANS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TORTICOLLIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TRIGGER FINGER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744			0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	TRISMUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WINGED SCAPULA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	28	3,1	0,46		Algorithm converged.	0,24	0,90	-0,016		Algorithm converged.	-0,030	-0,003	0,47		Algorithm converged.	0,25	0,90	0,0237		2,12		Algorithm converged.	1,11	4,07
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	4	0,7	1,30		Algorithm converged.	0,35	4,86	0,002		Algorithm converged.	-0,008	0,012	1,30		Algorithm converged.	0,35	4,81	0,6970		0,77		Algorithm converged.	0,21	2,86
	ACROCHORDON	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ACUTE MYELOID LEUKAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ADENOCARCINOMA PANCREAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ANOGENITAL WARTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BENIGN BREAST NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BENIGN NEOPLASM OF LACRIMAL DUCT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CANCER FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYELID TUMOUR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FIBROADENOMA OF BREAST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FIBROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMANGIOMA OF LIVER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGAMMAGLOBULINAEMIA BENIGN MONOCLONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LENTIGO MALIGNA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIPOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOBULAR BREAST CARCINOMA IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LUNG NEOPLASM MALIGNANT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MELANOCYTIC NAEVUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MENINGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONOCLONAL GAMMOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELODYSPLASTIC SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAEVUS HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEURILEMMOMA BENIGN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORAL FIBROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OVARIAN GERM CELL TERATOMA BENIGN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLARY THYROID CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARATHYROID TUMOUR BENIGN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYOGENIC GRANULOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEBORRHOEIC KERATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN PAPILLOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TUMOUR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UTERINE LEIOMYOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	34	66,7	42	2,3	29	69,0	0,90		Algorithm converged.	0,37	2,15	-0,024		Algorithm converged.	-0,214	0,167		0,97		Algorithm converged.	0,73	1,28	0,8063	0,9233	1,04		Algorithm converged.	0,78	1,37
		0 positive nodes, tumor > 1 cm	259	14,5	202	78,0	271	14,9	202	74,5	1,21		Algorithm converged.	0,81	1,81	0,035		Algorithm converged.	-0,038	0,107		1,05		Algorithm converged.	0,95	1,15	0,3502		0,96		Algorithm converged.	0,87	1,05
		1-3 positive nodes	891	50,0	628	70,5	905	49,7	601	66,4	1,21		Algorithm converged.	0,99	1,47	0,041		Algorithm converged.	-0,002	0,084		1,06		Algorithm converged.	1,00	1,13	0,0635		0,94		Algorithm converged.	0,88	1,00
		>= 4 positive nodes	582	32,6	391	67,2	604	33,2	389	64,4	1,13		Algorithm converged.	0,89	1,44	0,028		Algorithm converged.	-0,026	0,082		1,04		Algorithm converged.	0,96	1,13	0,3133		0,96		Algorithm converged.	0,88	1,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	4	0,4	1,27		Algorithm converged.	0,34	4,75	0,001		Algorithm converged.	-0,005	0,008	1,27		Algorithm converged.	0,34	4,71	0,7213		0,79		Algorithm converged.	0,21	2,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	4	0,7	1,30		Algorithm converged.	0,35	4,86	0,002		Algorithm converged.	-0,008	0,012	1,30		Algorithm converged.	0,35	4,81	0,6970		0,77		Algorithm converged.	0,21	2,86
	AKATHISIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALLODYNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AMNESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	ANOSMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHASIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ATAXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	AUDITORY NERVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BALANCE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	BELL'S PALSY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BRACHIAL PLEXOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BURNING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124			0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533			0,39		Algorithm converged.	0,08	1,98

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CAROTID ARTERY STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARPAL TUNNEL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.87480164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBELLAR SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CERVICAL RADICULOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICOBRACHIAL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLONUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COGNITIVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	6	0,7	1,02		Algorithm converged.	0,33	3,16	0,000		Algorithm converged.	-0,007	0,008	1,02		Algorithm converged.	0,33	3,14	0,9784		0,98		Algorithm converged.	0,32	3,04
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	7	1,2	0,89		Algorithm converged.	0,30	2,66	-0,001		Algorithm converged.	-0,013	0,011	0,89		Algorithm converged.	0,30	2,63	0,8325		1,12		Algorithm converged.	0,38	3,33
	COMPLEX REGIONAL PAIN SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
	COORDINATION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE			Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEMENTIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEPRESSED LEVEL OF CONSCIOUSNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	DISTURBANCE IN ATTENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	6	0,7	1,87		Algorithm converged.	0,69	5,09	0,006		Algorithm converged.	-0,003	0,015	1,86		Algorithm converged.	0,69	5,01	0,2186		0,54		Algorithm converged.	0,20	1,45
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	5	0,8	1,25		Algorithm converged.	0,38	4,11	0,002		Algorithm converged.	-0,009	0,013	1,25		Algorithm converged.	0,38	4,06	0,7158		0,80		Algorithm converged.	0,25	2,62
	DIZZINESS	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	3	7,1	1,11		Algorithm converged.	0,23	5,24	0,007		Algorithm converged.	-0,100	0,114	1,10		Algorithm converged.	0,26	4,64	0,8987	-	0,91		Algorithm converged.	0,22	3,84
		0 positive nodes, tumor > 1 cm	259	14,5	34	13,1	271	14,9	35	12,9	1,02		Algorithm converged.	0,61	1,69	0,002		Algorithm converged.	-0,055	0,059	1,02		Algorithm converged.	0,65	1,58	0,9421		0,98		Algorithm converged.	0,63	1,53
		1-3 positive nodes	891	50,0	108	12,1	905	49,7	104	11,5	1,06		Algorithm converged.	0,80	1,42	0,006		Algorithm converged.	-0,024	0,036	1,05		Algorithm converged.	0,82	1,36	0,6794		0,95		Algorithm converged.	0,74	1,22
		>= 4 positive nodes	582	32,6	69	11,9	604	33,2	68	11,3	1,06		Algorithm converged.	0,74	1,51	0,006		Algorithm converged.	-0,030	0,042	1,05		Algorithm converged.	0,77	1,44	0,7477		0,95		Algorithm converged.	0,69	1,30
	DIZZINESS POSTURAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,080	*	WARNING: The relative Hessian convergence criterion of 3.6622958501 is greater than the limit of 0.0001. The convergence is questionable.	-0,234	0,394	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	10	1,1	0,71		Algorithm converged.	0,27	1,87	-0,003		Algorithm converged.	-0,012	0,006	0,71		Algorithm converged.	0,27	1,86	0,4869		1,41		Algorithm converged.	0,54	3,68
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	7	1,2	1,49		Algorithm converged.	0,56	3,94	0,006		Algorithm converged.	-0,008	0,019	1,48		Algorithm converged.	0,57	3,87	0,4210		0,67		Algorithm converged.	0,26	1,76
	DYSARTHRIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	2	4,8	3,18		Algorithm converged.	0,62	16,22	0,090		Algorithm converged.	-0,025	0,204	2,88		Algorithm converged.	0,63	13,15	0,1715	-	0,35		Algorithm converged.	0,08	1,58
		0 positive nodes, tumor > 1 cm	259	14,5	39	15,1	271	14,9	56	20,7	0,68		Algorithm converged.	0,43	1,07	-0,056		Algorithm converged.	-0,121	0,009	0,73		Algorithm converged.	0,50	1,06	0,0951		1,37		Algorithm converged.	0,95	1,99
		1-3 positive nodes	891	50,0	156	17,5	905	49,7	128	14,1	1,29		Algorithm converged.	1,00	1,66	0,034		Algorithm converged.	0,000	0,067	1,24		Algorithm converged.	1,00	1,53	0,0513		0,81		Algorithm converged.	0,65	1,00
		>= 4 positive nodes	582	32,6	104	17,9	604	33,2	71	11,8	1,63		Algorithm converged.	1,18	2,26	0,061		Algorithm converged.	0,021	0,101	1,52		Algorithm converged.	1,15	2,01	0,0033		0,66		Algorithm converged.	0,50	0,87
	DYSKINESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTRIC SHOCK SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ESSENTIAL TREMOR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	FACIAL NERVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE CONVULSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FORMICATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEAD DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEAD TITUBATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	10	19,6	42	2,3	10	23,8	0,78		Algorithm converged.	0,29	2,10	-0,042		Algorithm converged.	-0,211	0,127	0,82		Algorithm converged.	0,38	1,79	0,6237	0,9364	1,21		Algorithm converged.	0,56	2,64
		0 positive nodes, tumor > 1 cm	259	14,5	59	22,8	271	14,9	68	25,1	0,88		Algorithm converged.	0,59	1,31	-0,023		Algorithm converged.	-0,096	0,049	0,91		Algorithm converged.	0,67	1,23	0,5335		1,10		Algorithm converged.	0,81	1,49
		1-3 positive nodes	891	50,0	199	22,3	905	49,7	204	22,5	0,99		Algorithm converged.	0,79	1,23	-0,002		Algorithm converged.	-0,041	0,037	0,99		Algorithm converged.	0,83	1,18	0,9163		1,01		Algorithm converged.	0,85	1,20
		>= 4 positive nodes	582	32,6	130	22,3	604	33,2	142	23,5	0,94		Algorithm converged.	0,71	1,23	-0,012		Algorithm converged.	-0,060	0,036	0,95		Algorithm converged.	0,77	1,17	0,6310		1,05		Algorithm converged.	0,85	1,30
	HEMIANOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	HYPERGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERPATHIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERSOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	8	3,0	1,05		Algorithm converged.	0,39	2,83	0,001		Algorithm converged.	-0,028	0,031	1,05		Algorithm converged.	0,40	2,75	0,9267		0,96		Algorithm converged.	0,36	2,51
		1-3 positive nodes	891	50,0	34	3,8	905	49,7	36	4,0	0,96		Algorithm converged.	0,59	1,54	-0,002		Algorithm converged.	-0,020	0,016	0,96		Algorithm converged.	0,61	1,52	0,8593		1,04		Algorithm converged.	0,66	1,65
		>= 4 positive nodes	582	32,6	21	3,6	604	33,2	19	3,1	1,15		Algorithm converged.	0,61	2,17	0,005		Algorithm converged.	-0,016	0,025	1,15		Algorithm converged.	0,62	2,11	0,6594		0,87		Algorithm converged.	0,47	1,60
	HYPOGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	HYPOSMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOTONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTERCOSTAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACUNAR INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LETHARGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	9	1,0	1,94		Algorithm converged.	0,86	4,37	0,009		Algorithm converged.	-0,002	0,020	1,92		Algorithm converged.	0,86	4,28	0,1116		0,52		Algorithm converged.	0,23	1,16
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	14	2,3	0,15		Algorithm converged.	0,03	0,64	-0,020		Algorithm converged.	-0,033	-0,007	0,15		Algorithm converged.	0,03	0,65	0,0113		6,74		Algorithm converged.	1,54	29,55
	LOSS OF CONSCIOUSNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	MEMORY IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	9	3,5	271	14,9	3	1,1	3,22		Algorithm converged.	0,86	12,01	0,024		Algorithm converged.	-0,002	0,049	3,14		Algorithm converged.	0,86	11,47	0,0835		0,32		Algorithm converged.	0,09	1,16
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	13	1,4	1,10		Algorithm converged.	0,51	2,34	0,001		Algorithm converged.	-0,010	0,013	1,09		Algorithm converged.	0,52	2,31	0,8145		0,91		Algorithm converged.	0,43	1,93
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	7	1,2	0,89		Algorithm converged.	0,30	2,66	-0,001		Algorithm converged.	-0,013	0,011	0,89		Algorithm converged.	0,30	2,63	0,8325		1,12		Algorithm converged.	0,38	3,33
	MENTAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIGRAINE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011	1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIGRAINE WITH AURA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MORTON'S NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCLE CONTRACTIONS INVOLUNTARY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCLE SPASTICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NERVE COMPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	5	0,6	2,04		Algorithm converged.	0,70	6,00	0,006		Algorithm converged.	-0,003	0,014	2,03		Algorithm converged.	0,70	5,92	0,1940		0,49		Algorithm converged.	0,17	1,43
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	12	2,0	0,69		Algorithm converged.	0,28	1,69	-0,006		Algorithm converged.	-0,021	0,008	0,69		Algorithm converged.	0,28	1,68	0,4158		1,45		Algorithm converged.	0,60	3,51
	NEURITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUROPATHY PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	12	28,6	0,40		Algorithm converged.	0,14	1,13	-0,148		Algorithm converged.	-0,315	0,018	0,48		Algorithm converged.	0,21	1,11	0,0864	0,2468	2,08		Algorithm converged.	0,90	4,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	47	18,1	271	14,9	41	15,1	1,24		Algorithm converged.	0,79	1,97	0,030		Algorithm converged.	-0,033	0,094	1,20		Algorithm converged.	0,82	1,76	0,3516		0,83		Algorithm converged.	0,57	1,22
		1-3 positive nodes	891	50,0	143	16,0	905	49,7	132	14,6	1,12		Algorithm converged.	0,87	1,45	0,015		Algorithm converged.	-0,019	0,048	1,10		Algorithm converged.	0,89	1,37	0,3893		0,91		Algorithm converged.	0,73	1,13
		>= 4 positive nodes	582	32,6	87	14,9	604	33,2	83	13,7	1,10		Algorithm converged.	0,80	1,53	0,012		Algorithm converged.	-0,028	0,052	1,09		Algorithm converged.	0,82	1,44	0,5534		0,92		Algorithm converged.	0,70	1,21
	NEUROTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016	0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64
		1-3 positive nodes	891	50,0	26	2,9	905	49,7	24	2,7	1,10		Algorithm converged.	0,63	1,94	0,003		Algorithm converged.	-0,013	0,018	1,10		Algorithm converged.	0,64	1,90	0,7319		0,91		Algorithm converged.	0,53	1,57
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	12	2,0	0,86		Algorithm converged.	0,37	2,01	-0,003		Algorithm converged.	-0,018	0,013	0,86		Algorithm converged.	0,38	1,99	0,7321		1,16		Algorithm converged.	0,50	2,66
	OCCIPITAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OPHTHALMIC MIGRAINE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORTHOSTATIC INTOLERANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	10	19,6	42	2,3	4	9,5	2,32		Algorithm converged.	0,67	8,01	0,101		Algorithm converged.	-0,040	0,241	2,06		Algorithm converged.	0,70	6,09	0,1922	0,5229	0,49		Algorithm converged.	0,16	1,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	26	10,0	271	14,9	31	11,4	0,86		Algorithm converged.	0,50	1,50	-0,014		Algorithm converged.	-0,067	0,039	0,88		Algorithm converged.	0,54	1,44	0,6033		1,14		Algorithm converged.	0,70	1,86
		1-3 positive nodes	891	50,0	101	11,3	905	49,7	95	10,5	1,09		Algorithm converged.	0,81	1,47	0,008		Algorithm converged.	-0,020	0,037	1,08		Algorithm converged.	0,83	1,41	0,5690		0,93		Algorithm converged.	0,71	1,21
		>= 4 positive nodes	582	32,6	63	10,8	604	33,2	58	9,6	1,14		Algorithm converged.	0,78	1,66	0,012		Algorithm converged.	-0,022	0,047	1,13		Algorithm converged.	0,80	1,58	0,4873		0,89		Algorithm converged.	0,63	1,24
	PAROSMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	1	0,1	6,13		Algorithm converged.	0,74	51,01	0,006		Algorithm converged.	0,000	0,011	6,09		Algorithm converged.	0,74	50,52	0,0940		0,16		Algorithm converged.	0,02	1,36
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL MOTOR NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	8	0,9	0,76		Algorithm converged.	0,26	2,20	-0,002		Algorithm converged.	-0,010	0,006		0,76		Algorithm converged.	0,27	2,19	0,6130		1,31		Algorithm converged.	0,46	3,77
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	1	0,2	5,23		Algorithm converged.	0,61	44,86	0,007		Algorithm converged.	-0,001	0,015		5,19		Algorithm converged.	0,61	44,28	0,1323		0,19		Algorithm converged.	0,02	1,64
	PERIPHERAL PARALYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIPHERAL SENSORY NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	10	19,6	42	2,3	7	16,7	1,22		Algorithm converged.	0,42	3,54	0,029		Algorithm converged.	-0,127	0,186		1,18		Algorithm converged.	0,49	2,82	0,7159	0,2545	0,85		Algorithm converged.	0,35	2,04
		0 positive nodes, tumor > 1 cm	259	14,5	57	22,0	271	14,9	77	28,4	0,71		Algorithm converged.	0,48	1,06	-0,064		Algorithm converged.	-0,138	0,010		0,77		Algorithm converged.	0,58	1,04	0,0919		1,29		Algorithm converged.	0,96	1,74
		1-3 positive nodes	891	50,0	155	17,4	905	49,7	145	16,0	1,10		Algorithm converged.	0,86	1,41	0,014		Algorithm converged.	-0,021	0,048		1,09		Algorithm converged.	0,88	1,34	0,4352		0,92		Algorithm converged.	0,75	1,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	98	16,8	604	33,2	93	15,4	1,11		Algorithm converged.	0,82	1,52	0,014		Algorithm converged.	-0,027	0,056	1,09		Algorithm converged.	0,84	1,42	0,4998		0,91		Algorithm converged.	0,71	1,19
	PHANTOM LIMB SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POLYNEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150647 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	6	2,2	1,23		Algorithm converged.	0,41	3,70	0,005		Algorithm converged.	-0,022	0,031		1,22		Algorithm converged.	0,42	3,58	0,7167		0,82		Algorithm converged.	0,28	2,41
		1-3 positive nodes	891	50,0	22	2,5	905	49,7	20	2,2	1,12		Algorithm converged.	0,61	2,07	0,003		Algorithm converged.	-0,011	0,017		1,12		Algorithm converged.	0,61	2,03	0,7164		0,90		Algorithm converged.	0,49	1,63
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	12	2,0	1,04		Algorithm converged.	0,46	2,33	0,001		Algorithm converged.	-0,015	0,017		1,04		Algorithm converged.	0,47	2,29	0,9268		0,96		Algorithm converged.	0,44	2,13
	PRESYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075		0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	8	0,9	0,63		Algorithm converged.	0,21	1,94	-0,003		Algorithm converged.	-0,011	0,005	0,63		Algorithm converged.	0,21	1,93	0,4238		1,58		Algorithm converged.	0,52	4,80
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	2	0,3	3,14		Algorithm converged.	0,63	15,60	0,007		Algorithm converged.	-0,002	0,016	3,11		Algorithm converged.	0,63	15,36	0,1632		0,32		Algorithm converged.	0,07	1,58
	PSYCHOGENIC SEIZURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOMOTOR HYPERACTIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYRAMIDAL TRACT SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	RESTLESS LEGS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	3	1,1	1,05		Algorithm converged.	0,21	5,23	0,001		Algorithm converged.	-0,018	0,019		1,05		Algorithm converged.	0,21	5,14	0,9555			0,96		Algorithm converged.	0,19	4,69
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009		1,52		Algorithm converged.	0,43	5,38	0,5131			0,66		Algorithm converged.	0,19	2,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCIATICA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	11	1,2	0,55		Algorithm converged.	0,20	1,50	-0,005		Algorithm converged.	-0,014	0,004	0,55		Algorithm converged.	0,21	1,49	0,2425		1,80		Algorithm converged.	0,67	4,86
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	SEIZURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	SENSORY DISTURBANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SENSORY LOSS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SOMNOLENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	7	0,8	1,75		Algorithm converged.	0,69	4,47	0,006		Algorithm converged.	-0,004	0,015	1,74		Algorithm converged.	0,69	4,40	0,2412		0,57		Algorithm converged.	0,23	1,45
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075	0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	9	1,0	1,59		Algorithm converged.	0,68	3,69	0,006		Algorithm converged.	-0,005	0,016	1,58		Algorithm converged.	0,69	3,63	0,2814		0,63		Algorithm converged.	0,28	1,45
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	7	1,2	1,64		Algorithm converged.	0,63	4,27	0,007		Algorithm converged.	-0,007	0,021	1,63		Algorithm converged.	0,64	4,18	0,3082		0,61		Algorithm converged.	0,24	1,57
	TASTE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	2	4,8	2,67		Algorithm converged.	0,51	13,97	0,070		Algorithm converged.	-0,039	0,179	2,47		Algorithm converged.	0,53	11,61	0,2519	-	0,40		Algorithm converged.	0,09	1,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	24	9,3	271	14,9	17	6,3	1,53		Algorithm converged.	0,80	2,91	0,030		Algorithm converged.	-0,016	0,076	1,48		Algorithm converged.	0,81	2,68	0,2006		0,68		Algorithm converged.	0,37	1,23
		1-3 positive nodes	891	50,0	74	8,3	905	49,7	60	6,6	1,28		Algorithm converged.	0,90	1,82	0,017		Algorithm converged.	-0,008	0,041	1,25		Algorithm converged.	0,90	1,74	0,1778		0,80		Algorithm converged.	0,58	1,11
		>= 4 positive nodes	582	32,6	45	7,7	604	33,2	45	7,5	1,04		Algorithm converged.	0,68	1,60	0,003		Algorithm converged.	-0,027	0,033	1,04		Algorithm converged.	0,70	1,54	0,8547		0,96		Algorithm converged.	0,65	1,43
	TENSION HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THALAMIC INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	TOXIC NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TREMOR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	3	0,3	2,38		Algorithm converged.	0,61	9,24	0,005		Algorithm converged.	-0,002	0,011	2,37		Algorithm converged.	0,61	9,14	0,2101		0,42		Algorithm converged.	0,11	1,63
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	TRIGEMINAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	VASCULAR ENCEPHALOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VOCAL CORD PARESIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PRODUCT ISSUE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003	0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	DEVICE BREAKAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE CONNECTION ISSUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE DEFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE EXTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE ISSUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE MALFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE OCCLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THROMBOSIS IN DEVICE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	13	25,5	42	2,3	13	31,0	0,76		Algorithm converged.	0,31	1,89	-0,055		Algorithm converged.	-0,239	0,129		0,82		Algorithm converged.	0,43	1,58	0,5590	0,6131	1,21		Algorithm converged.	0,63	2,33
		0 positive nodes, tumor > 1 cm	259	14,5	65	25,1	271	14,9	72	26,6	0,93		Algorithm converged.	0,63	1,37	-0,015		Algorithm converged.	-0,089	0,060		0,94		Algorithm converged.	0,71	1,26	0,6990		1,06		Algorithm converged.	0,79	1,41
		1-3 positive nodes	891	50,0	247	27,7	905	49,7	222	24,5	1,18		Algorithm converged.	0,96	1,46	0,032		Algorithm converged.	-0,009	0,073		1,13		Algorithm converged.	0,97	1,32	0,1241		0,88		Algorithm converged.	0,76	1,03
		>= 4 positive nodes	582	32,6	154	26,5	604	33,2	150	24,8	1,09		Algorithm converged.	0,84	1,41	0,016		Algorithm converged.	-0,033	0,066		1,07		Algorithm converged.	0,88	1,29	0,5215		0,94		Algorithm converged.	0,77	1,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADJUSTMENT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ADJUSTMENT DISORDER WITH DEPRESSED MOOD	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AFFECT LABILITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	AFFECTIVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	AGITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009		2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	AGORAPHOBIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	4	9,5	0,59		Algorithm converged.	0,13	2,82	-0,036		Algorithm converged.	-0,146	0,073		0,62		Algorithm converged.	0,15	2,61	0,5120	-	1,62		Algorithm converged.	0,38	6,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	18	6,9	271	14,9	9	3,3	2,17		Algorithm converged.	0,96	4,93	0,036		Algorithm converged.	-0,001	0,074	2,09		Algorithm converged.	0,96	4,57	0,0641		0,48		Algorithm converged.	0,22	1,04
		1-3 positive nodes	891	50,0	47	5,3	905	49,7	36	4,0	1,34		Algorithm converged.	0,86	2,10	0,013		Algorithm converged.	-0,006	0,032	1,33		Algorithm converged.	0,87	2,03	0,1922		0,75		Algorithm converged.	0,49	1,15
		>= 4 positive nodes	582	32,6	41	7,0	604	33,2	28	4,6	1,56		Algorithm converged.	0,95	2,56	0,024		Algorithm converged.	-0,003	0,051	1,52		Algorithm converged.	0,95	2,42	0,0789		0,66		Algorithm converged.	0,41	1,05
	ANXIETY DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk										
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	CONFUSIONAL STATE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DELUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSED MOOD	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	8	0,9	1,53		Algorithm converged.	0,62	3,76	0,005		Algorithm converged.	-0,005	0,014		1,52		Algorithm converged.	0,63	3,71	0,3537			0,66		Algorithm converged.	0,27	1,60						
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009		1,56		Algorithm converged.	0,26	9,28	0,6271			0,64		Algorithm converged.	0,11	3,83						
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-		2,43		Algorithm converged.	0,23	25,86						
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	14	5,2	0,51		Algorithm converged.	0,20	1,28	-0,025		Algorithm converged.	-0,058	0,008		0,52		Algorithm converged.	0,21	1,28	0,1542			1,91		Algorithm converged.	0,78	4,66						
		1-3 positive nodes	891	50,0	45	5,1	905	49,7	33	3,6	1,41		Algorithm converged.	0,89	2,22	0,014		Algorithm converged.	-0,005	0,033		1,39		Algorithm converged.	0,89	2,15	0,1464			0,72		Algorithm converged.	0,47	1,12						
		>= 4 positive nodes	582	32,6	29	5,0	604	33,2	29	4,8	1,04		Algorithm converged.	0,61	1,76	0,002		Algorithm converged.	-0,023	0,026		1,04		Algorithm converged.	0,63	1,71	0,8848			0,96		Algorithm converged.	0,58	1,59						
	DEPRESSIVE SYMPTOM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISORIENTATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMOTIONAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMOTIONAL DISTRESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENURESIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENITO-PELVIC PAIN/PENETRATION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HALLUCINATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ILLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	7	16,7	0,80		Algorithm converged.	0,25	2,48	-0,029		Algorithm converged.	-0,176	0,118		0,82		Algorithm converged.	0,31	2,16	0,6933	0,8869	1,21		Algorithm converged.	0,46	3,19
		0 positive nodes, tumor > 1 cm	259	14,5	38	14,7	271	14,9	46	17,0	0,84		Algorithm converged.	0,53	1,34	-0,023		Algorithm converged.	-0,085	0,039		0,86		Algorithm converged.	0,58	1,28	0,4689		1,16		Algorithm converged.	0,78	1,72
		1-3 positive nodes	891	50,0	148	16,6	905	49,7	148	16,4	1,02		Algorithm converged.	0,79	1,31	0,003		Algorithm converged.	-0,032	0,037		1,02		Algorithm converged.	0,82	1,25	0,8833		0,98		Algorithm converged.	0,80	1,21
		>= 4 positive nodes	582	32,6	92	15,8	604	33,2	100	16,6	0,95		Algorithm converged.	0,69	1,29	-0,007		Algorithm converged.	-0,049	0,034		0,95		Algorithm converged.	0,74	1,24	0,7264		1,05		Algorithm converged.	0,81	1,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
	IRRITABILITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	7	0,8	0,43		Algorithm converged.	0,11	1,68	-0,004		Algorithm converged.	-0,011	0,002		0,44		Algorithm converged.	0,11	1,68	0,2270			2,30		Algorithm converged.	0,60	8,86	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011		1,38		Algorithm converged.	0,31	6,16	0,6698			0,72		Algorithm converged.	0,16	3,21	
	LIBIDO DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010	5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	5	0,8	1,25		Algorithm converged.	0,38	4,11	0,002		Algorithm converged.	-0,009	0,013	1,25		Algorithm converged.	0,38	4,06	0,7158		0,80		Algorithm converged.	0,25	2,62
	LIBIDO DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOSS OF LIBIDO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MAJOR DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MANIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	MENTAL STATUS CHANGES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIXED ANXIETY AND DEPRESSIVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MOOD ALTERED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	7	0,8	1,31		Algorithm converged.	0,49	3,53	0,002		Algorithm converged.	-0,006	0,011		1,31		Algorithm converged.	0,49	3,49	0,5948		0,77		Algorithm converged.	0,29	2,05
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014		1,56		Algorithm converged.	0,44	5,49	0,4912		0,64		Algorithm converged.	0,18	2,26
	MOOD SWINGS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	6	0,7	1,02		Algorithm converged.	0,33	3,16	0,000		Algorithm converged.	-0,007	0,008	1,02		Algorithm converged.	0,33	3,14	0,9784		0,98		Algorithm converged.	0,32	3,04
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	NERVOUSNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NIGHTMARE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOPHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORGANIC BRAIN SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PANIC ATTACK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PARASOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSISTENT DEPRESSIVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERSONALITY CHANGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POOR QUALITY SLEEP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PSYCHIATRIC SYMPTOM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PSYCHOTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	REACTIVE PSYCHOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RESTLESSNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	SELF ESTEEM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SLEEP DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	6	2,2	0,69		Algorithm converged.	0,19	2,48	-0,007		Algorithm converged.	-0,030	0,016	0,70		Algorithm converged.	0,20	2,44	0,5734		1,43		Algorithm converged.	0,41	5,02
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	5	0,6	2,67		Algorithm converged.	0,95	7,51	0,009		Algorithm converged.	0,000	0,018	2,64		Algorithm converged.	0,95	7,38	0,0639		0,38		Algorithm converged.	0,14	1,06
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	5	0,8	1,04		Algorithm converged.	0,30	3,60	0,000		Algorithm converged.	-0,010	0,011	1,04		Algorithm converged.	0,30	3,57	0,9530		0,96		Algorithm converged.	0,28	3,31
	STRESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625			0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	SUICIDAL IDEATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
	SUICIDE ATTEMPT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE				NE	NE	NE	-			NE		NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TEARFULNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	THINKING ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOMITING PSYCHOGENIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	3	7,1	1,41		Algorithm converged.	0,32	6,29	0,027		Algorithm converged.	-0,086	0,139		1,37		Algorithm converged.	0,35	5,41	0,6510	-	0,73		Algorithm converged.	0,18	2,87
		0 positive nodes, tumor > 1 cm	259	14,5	20	7,7	271	14,9	20	7,4	1,05		Algorithm converged.	0,55	2,00	0,003		Algorithm converged.	-0,042	0,048		1,05		Algorithm converged.	0,58	1,90	0,8816		0,96		Algorithm converged.	0,53	1,73
		1-3 positive nodes	891	50,0	74	8,3	905	49,7	75	8,3	1,00		Algorithm converged.	0,72	1,40	0,000		Algorithm converged.	-0,025	0,026		1,00		Algorithm converged.	0,74	1,36	0,9890		1,00		Algorithm converged.	0,73	1,36
		>= 4 positive nodes	582	32,6	39	6,7	604	33,2	45	7,5	0,89		Algorithm converged.	0,57	1,39	-0,007		Algorithm converged.	-0,037	0,022		0,90		Algorithm converged.	0,59	1,36	0,6153		1,11		Algorithm converged.	0,74	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	1	0,2	6,28		Algorithm converged.	0,75	52,33	0,009		Algorithm converged.	0,000	0,017	6,23		Algorithm converged.	0,75	51,56	0,0900		0,16		Algorithm converged.	0,02	1,33
	BLADDER DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLADDER PROLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COSTOVERTEBRAL ANGLE TENDERNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CYSTITIS HAEMORRHAGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CYSTITIS INTERSTITIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS NONINFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
	DYSURIA	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114	2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	7	2,6	0,59		Algorithm converged.	0,17	2,05	-0,010		Algorithm converged.	-0,035	0,014	0,60		Algorithm converged.	0,18	2,02	0,4073		1,67		Algorithm converged.	0,50	5,65
		1-3 positive nodes	891	50,0	30	3,4	905	49,7	28	3,1	1,09		Algorithm converged.	0,65	1,84	0,003		Algorithm converged.	-0,014	0,019	1,09		Algorithm converged.	0,66	1,81	0,7435		0,92		Algorithm converged.	0,55	1,53
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	19	3,1	0,87		Algorithm converged.	0,44	1,71	-0,004		Algorithm converged.	-0,023	0,015	0,87		Algorithm converged.	0,45	1,68	0,6869		1,14		Algorithm converged.	0,59	2,20
	HAEMATURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	5	0,6	1,02		Algorithm converged.	0,29	3,52	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,30	3,50	0,9803		0,98		Algorithm converged.	0,29	3,39
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	HYPERTONIC BLADDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE					
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37					
	LEUKOCYTURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICTURITION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MICTURITION URGENCY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	NEPHROLITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	NOCTURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POLLAKIURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	5	1,8	0,62		Algorithm converged.	0,15	2,64	-0,007		Algorithm converged.	-0,028	0,014		0,63		Algorithm converged.	0,15	2,60	0,5209		1,59		Algorithm converged.	0,38	6,60
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	12	1,3	1,02		Algorithm converged.	0,45	2,27	0,000		Algorithm converged.	-0,010	0,011		1,02		Algorithm converged.	0,46	2,25	0,9693		0,98		Algorithm converged.	0,44	2,18
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	7	1,2	0,89		Algorithm converged.	0,30	2,66	-0,001		Algorithm converged.	-0,013	0,011		0,89		Algorithm converged.	0,30	2,63	0,8325		1,12		Algorithm converged.	0,38	3,33
	POLYURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
	PROTEINURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RENAL FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003		0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	RENAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	STRANGURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRESS URINARY INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETEROLITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URGE INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY HESITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	URINARY RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	URINARY TRACT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY TRACT OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY TRACT PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	3	0,3	2,72		Algorithm converged.	0,72	10,30	0,006		Algorithm converged.	-0,002	0,013	2,71		Algorithm converged.	0,72	10,18	0,1401		0,37		Algorithm converged.	0,10	1,39
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URINE ODOUR ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROGENITAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	12	23,5	42	2,3	9	21,4	1,13		Algorithm converged.	0,42	3,01	0,021		Algorithm converged.	-0,149	0,191		1,10		Algorithm converged.	0,51	2,35	0,8098	0,9590	0,91		Algorithm converged.	0,43	1,95
		0 positive nodes, tumor > 1 cm	259	14,5	47	18,1	271	14,9	44	16,2	1,14		Algorithm converged.	0,73	1,80	0,019		Algorithm converged.	-0,045	0,083		1,12		Algorithm converged.	0,77	1,62	0,5601		0,89		Algorithm converged.	0,62	1,30
		1-3 positive nodes	891	50,0	171	19,2	905	49,7	163	18,0	1,08		Algorithm converged.	0,85	1,37	0,012		Algorithm converged.	-0,024	0,048		1,07		Algorithm converged.	0,88	1,29	0,5203		0,94		Algorithm converged.	0,77	1,14
		>= 4 positive nodes	582	32,6	92	15,8	604	33,2	96	15,9	0,99		Algorithm converged.	0,73	1,36	-0,001		Algorithm converged.	-0,042	0,041		0,99		Algorithm converged.	0,77	1,29	0,9675		1,01		Algorithm converged.	0,77	1,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMENORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	16	1,8	0,82		Algorithm converged.	0,39	1,72	-0,003		Algorithm converged.	-0,015	0,009	0,83		Algorithm converged.	0,40	1,71	0,6041		1,21		Algorithm converged.	0,59	2,50
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	11	1,8	1,23		Algorithm converged.	0,55	2,77	0,004		Algorithm converged.	-0,012	0,020	1,23		Algorithm converged.	0,55	2,72	0,6147		0,82		Algorithm converged.	0,37	1,81
	ATROPHIC VULVOVAGINITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BARTHOLIN'S CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ATROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CALCIFICATIONS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	BREAST DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	BREAST DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST ENGORGEMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST ENLARGEMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37	
	BREAST HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREAST INDURATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005		0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	BREAST MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	8	0,9	2,18		Algorithm converged.	0,94	5,08	0,010		Algorithm converged.	-0,001	0,021	2,16		Algorithm converged.	0,94	4,98	0,0710		0,46		Algorithm converged.	0,20	1,07
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005	0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	BREAST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	4	9,5	1,77		Algorithm converged.	0,49	6,34	0,062		Algorithm converged.	-0,072	0,195	1,65		Algorithm converged.	0,53	5,09	0,3862	0,7378	0,61		Algorithm converged.	0,20	1,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	13	4,8	1,05		Algorithm converged.	0,48	2,31	0,002		Algorithm converged.	-0,035	0,039	1,05		Algorithm converged.	0,49	2,21	0,9057		0,96		Algorithm converged.	0,45	2,02
		1-3 positive nodes	891	50,0	38	4,3	905	49,7	45	5,0	0,85		Algorithm converged.	0,55	1,32	-0,007		Algorithm converged.	-0,026	0,012	0,86		Algorithm converged.	0,56	1,31	0,4757		1,17		Algorithm converged.	0,76	1,78
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	18	3,0	0,98		Algorithm converged.	0,50	1,92	-0,001		Algorithm converged.	-0,020	0,019	0,98		Algorithm converged.	0,51	1,88	0,9520		1,02		Algorithm converged.	0,53	1,96
	BREAST SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 36.470269688 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,071	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST TENDERNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	5	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9998		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CERVICAL POLYP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSMENORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSPAREUNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	8	0,9	1,02		Algorithm converged.	0,38	2,72	0,000		Algorithm converged.	-0,009	0,009	1,02		Algorithm converged.	0,38	2,69	0,9750		0,98		Algorithm converged.	0,37	2,61
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013	1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41
	ECTROPION OF CERVIX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ENDOMETRIAL HYPERPLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOMETRIAL HYPERTROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ENDOMETRIAL THICKENING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ENDOMETRIOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERECTILE DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GALACTORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENITAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENITAL PROLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GENITAL RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENITAL TRACT INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENITAL ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	HEAVY MENSTRUAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875			0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014		2,59		Algorithm converged.	0,51	13,32	0,2533			0,39		Algorithm converged.	0,08	1,98

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERMENSTRUAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	4	0,4	1,27		Algorithm converged.	0,34	4,75	0,001		Algorithm converged.	-0,005	0,008	1,27		Algorithm converged.	0,34	4,71	0,7213		0,79		Algorithm converged.	0,21	2,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001	0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11
	MENOMETRORRHAGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MENOPAUSAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MENOPAUSAL SYMPTOMS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455			0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342			0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	MENSTRUAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006		1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	MENSTRUATION IRREGULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	6	2,2	1,41		Algorithm converged.	0,48	4,11	0,009		Algorithm converged.	-0,019	0,036		1,40		Algorithm converged.	0,49	3,97	0,5322		0,72		Algorithm converged.	0,25	2,04
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	21	2,3	0,72		Algorithm converged.	0,37	1,41	-0,006		Algorithm converged.	-0,019	0,007		0,73		Algorithm converged.	0,38	1,40	0,3378		1,38		Algorithm converged.	0,72	2,66
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	9	1,5	0,80		Algorithm converged.	0,30	2,18	-0,003		Algorithm converged.	-0,016	0,010		0,81		Algorithm converged.	0,30	2,15	0,6687		1,24		Algorithm converged.	0,46	3,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NIPPLE EXUDATE BLOODY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	OLIGOMENORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OVARIAN CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	3	0,3	1,70		Algorithm converged.	0,40	7,12	0,002		Algorithm converged.	-0,004	0,008	1,69		Algorithm converged.	0,41	7,06	0,4701		0,59		Algorithm converged.	0,14	2,46
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PELVIC DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC FLOOR MUSCLE WEAKNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	5	1,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	7	0,8	0,14		Algorithm converged.	0,02	1,17	-0,007		Algorithm converged.	-0,013	0,000	0,15		Algorithm converged.	0,02	1,18	0,0707		6,89		Algorithm converged.	0,85	55,90
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	PERINEAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE				NE	NE					
	PERINEAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE				NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERINEAL ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PREMATURE MENOPAUSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURITUS GENITAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	REPRODUCTIVE TRACT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETRACTED NIPPLE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UTERINE POLYP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VAGINAL CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	VAGINAL DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	12	1,3	1,53		Algorithm converged.	0,73	3,20	0,007		Algorithm converged.	-0,005	0,019	1,52		Algorithm converged.	0,74	3,14	0,2547		0,66		Algorithm converged.	0,32	1,35
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	7	1,2	1,19		Algorithm converged.	0,43	3,30	0,002		Algorithm converged.	-0,011	0,015	1,19		Algorithm converged.	0,43	3,25	0,7400		0,84		Algorithm converged.	0,31	2,31
	VAGINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	8	0,9	0,51		Algorithm converged.	0,15	1,69	-0,004		Algorithm converged.	-0,012	0,003	0,51		Algorithm converged.	0,15	1,68	0,2671		1,97		Algorithm converged.	0,60	6,52
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	9	1,5	0,46		Algorithm converged.	0,14	1,49	-0,008		Algorithm converged.	-0,020	0,004	0,46		Algorithm converged.	0,14	1,49	0,1957		2,17		Algorithm converged.	0,67	7,00
	VAGINAL LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VULVAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VULVAL ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAR EROSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VULVOVAGINAL BURNING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996293 9 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	2	4,8	1,25		Algorithm converged.	0,20	7,85	0,011		Algorithm converged.	-0,080	0,102	1,24		Algorithm converged.	0,22	7,05	0,8121	-	0,81		Algorithm converged.	0,14	4,62
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	8	3,0	0,78		Algorithm converged.	0,27	2,28	-0,006		Algorithm converged.	-0,034	0,021	0,78		Algorithm converged.	0,28	2,23	0,6493		1,27		Algorithm converged.	0,45	3,62
		1-3 positive nodes	891	50,0	36	4,0	905	49,7	29	3,2	1,27		Algorithm converged.	0,77	2,09	0,008		Algorithm converged.	-0,009	0,026	1,26		Algorithm converged.	0,78	2,04	0,3441		0,79		Algorithm converged.	0,49	1,28
		>= 4 positive nodes	582	32,6	20	3,4	604	33,2	25	4,1	0,82		Algorithm converged.	0,45	1,50	-0,007		Algorithm converged.	-0,029	0,015	0,83		Algorithm converged.	0,47	1,48	0,5273		1,20		Algorithm converged.	0,68	2,14
	VULVOVAGINAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VULVOVAGINAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	3	0,3	1,70		Algorithm converged.	0,40	7,12	0,002		Algorithm converged.	-0,004	0,008		1,69		Algorithm converged.	0,41	7,06	0,4701		0,59		Algorithm converged.	0,14	2,46	
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007		0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72	
	VULVOVAGINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VULVOVAGINAL RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	29	56,9	42	2,3	19	45,2	1,60		Algorithm converged.	0,70	3,63	0,116		Algorithm converged.	-0,087	0,319		1,26		Algorithm converged.	0,83	1,89	0,2739	0,6886	0,80		Algorithm converged.	0,53	1,20	
		0 positive nodes, tumor > 1 cm	259	14,5	131	50,6	271	14,9	136	50,2	1,02		Algorithm converged.	0,72	1,43	0,004		Algorithm converged.	-0,081	0,089		1,01		Algorithm converged.	0,85	1,19	0,9276		0,99		Algorithm converged.	0,84	1,17	
		1-3 positive nodes	891	50,0	433	48,6	905	49,7	397	43,9	1,21		Algorithm converged.	1,00	1,46	0,047		Algorithm converged.	0,001	0,093		1,11		Algorithm converged.	1,00	1,22	0,0447		0,90		Algorithm converged.	0,82	1,00	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	256	44,0	604	33,2	239	39,6	1,20		Algorithm converged.	0,95	1,51	0,044		Algorithm converged.	-0,012	0,100	1,11		Algorithm converged.	0,97	1,27	0,1234		0,90		Algorithm converged.	0,79	1,03
	ACUTE RESPIRATORY DISTRESS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALLERGIC SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	APHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744			0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASTHMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	ATELECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHIAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
	BRONCHIAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BRONCHIECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BRONCHOPNEUMOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20	
	BRONCHOSTENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARRH	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908			0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004		0,42		Algorithm converged.	0,08	2,13	0,2922			2,41		Algorithm converged.	0,47	12,37
	CHOKING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	7	16,7	0,93		Algorithm converged.	0,31	2,82	-0,010		Algorithm converged.	-0,160	0,141		0,94		Algorithm converged.	0,37	2,38	0,8982	0,7775	1,06		Algorithm converged.	0,42	2,69
		0 positive nodes, tumor > 1 cm	259	14,5	43	16,6	271	14,9	49	18,1	0,90		Algorithm converged.	0,57	1,42	-0,015		Algorithm converged.	-0,079	0,050		0,92		Algorithm converged.	0,63	1,33	0,6534		1,09		Algorithm converged.	0,75	1,58
		1-3 positive nodes	891	50,0	149	16,7	905	49,7	136	15,0	1,14		Algorithm converged.	0,88	1,46	0,017		Algorithm converged.	-0,017	0,051		1,11		Algorithm converged.	0,90	1,38	0,3259		0,90		Algorithm converged.	0,73	1,11
		>= 4 positive nodes	582	32,6	85	14,6	604	33,2	91	15,1	0,96		Algorithm converged.	0,70	1,33	-0,005		Algorithm converged.	-0,045	0,036		0,97		Algorithm converged.	0,74	1,27	0,8232		1,03		Algorithm converged.	0,79	1,36
	DRY THROAT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	DYSAESTHESIA PHARYNX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DYSPHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	9	1,0	1,47		Algorithm converged.	0,63	3,47	0,005		Algorithm converged.	-0,006	0,015		1,47		Algorithm converged.	0,63	3,41	0,3739			0,68		Algorithm converged.	0,29	1,59
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	8	1,3	1,17		Algorithm converged.	0,45	3,05	0,002		Algorithm converged.	-0,011	0,016		1,17		Algorithm converged.	0,45	3,01	0,7482			0,86		Algorithm converged.	0,33	2,20
	DYSPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082		0,66		Algorithm converged.	0,19	2,30	0,5128	-		1,52		Algorithm converged.	0,43	5,30
		0 positive nodes, tumor > 1 cm	259	14,5	40	15,4	271	14,9	33	12,2	1,32		Algorithm converged.	0,80	2,16	0,033		Algorithm converged.	-0,026	0,091		1,27		Algorithm converged.	0,83	1,95	0,2768			0,79		Algorithm converged.	0,51	1,21
		1-3 positive nodes	891	50,0	95	10,7	905	49,7	112	12,4	0,85		Algorithm converged.	0,63	1,13	-0,017		Algorithm converged.	-0,047	0,012		0,86		Algorithm converged.	0,67	1,11	0,2562			1,16		Algorithm converged.	0,90	1,50
		>= 4 positive nodes	582	32,6	55	9,5	604	33,2	54	8,9	1,06		Algorithm converged.	0,72	1,58	0,005		Algorithm converged.	-0,028	0,038		1,06		Algorithm converged.	0,74	1,51	0,7613			0,95		Algorithm converged.	0,66	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPNOEA EXERTIONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2	0,52		Algorithm converged.	0,13	2,09	-0,011		Algorithm converged.	-0,032	0,011	0,52		Algorithm converged.	0,13	2,07	0,3559		1,91		Algorithm converged.	0,48	7,56
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	15	1,7	0,54		Algorithm converged.	0,23	1,27	-0,008		Algorithm converged.	-0,018	0,003	0,54		Algorithm converged.	0,23	1,27	0,1590		1,85		Algorithm converged.	0,79	4,33
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	11	1,8	1,13		Algorithm converged.	0,50	2,59	0,002		Algorithm converged.	-0,013	0,018	1,13		Algorithm converged.	0,50	2,55	0,7640		0,88		Algorithm converged.	0,39	1,99
	EPISTAXIS	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	5	11,9	1,38		Algorithm converged.	0,41	4,57	0,038		Algorithm converged.	-0,102	0,178	1,32		Algorithm converged.	0,47	3,73	0,6032	0,9636	0,76		Algorithm converged.	0,27	2,15
		0 positive nodes, tumor > 1 cm	259	14,5	38	14,7	271	14,9	33	12,2	1,24		Algorithm converged.	0,75	2,05	0,025		Algorithm converged.	-0,033	0,083	1,20		Algorithm converged.	0,78	1,86	0,4002		0,83		Algorithm converged.	0,54	1,28
		1-3 positive nodes	891	50,0	169	19,0	905	49,7	127	14,0	1,43		Algorithm converged.	1,12	1,84	0,049		Algorithm converged.	0,015	0,084	1,35		Algorithm converged.	1,09	1,67	0,0051		0,74		Algorithm converged.	0,60	0,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	89	15,3	604	33,2	73	12,1	1,31		Algorithm converged.	0,94	1,83	0,032		Algorithm converged.	-0,007	0,071	1,27		Algorithm converged.	0,95	1,69	0,1091		0,79		Algorithm converged.	0,59	1,05
	HAEMOPTYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HICCUPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	7	0,8	0,14		Algorithm converged.	0,02	1,17	-0,007		Algorithm converged.	-0,013	0,000	0,15		Algorithm converged.	0,02	1,18	0,0707		6,89		Algorithm converged.	0,85	55,90
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	HYPERVENTILATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERSTITIAL LUNG DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LARYNGEAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGEAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LARYNGEAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LARYNGEAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LUNG CONSOLIDATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG INFILTRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	7	2,6	0,74		Algorithm converged.	0,23	2,37	-0,007		Algorithm converged.	-0,032	0,019	0,75		Algorithm converged.	0,24	2,33	0,6151		1,34		Algorithm converged.	0,43	4,16
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	27	3,0	0,67		Algorithm converged.	0,37	1,23	-0,010		Algorithm converged.	-0,024	0,005	0,68		Algorithm converged.	0,38	1,22	0,1946		1,48		Algorithm converged.	0,82	2,66
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	14	2,3	0,89		Algorithm converged.	0,41	1,93	-0,003		Algorithm converged.	-0,019	0,014	0,89		Algorithm converged.	0,41	1,91	0,7635		1,12		Algorithm converged.	0,52	2,41

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL CRUSTING	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	6	0,7	1,36		Algorithm converged.	0,47	3,93	0,002		Algorithm converged.	-0,006	0,010	1,35		Algorithm converged.	0,47	3,89	0,5730		0,74		Algorithm converged.	0,26	2,12
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	NASAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114	2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	5	1,8	0,62		Algorithm converged.	0,15	2,64	-0,007		Algorithm converged.	-0,028	0,014	0,63		Algorithm converged.	0,15	2,60	0,5209		1,59		Algorithm converged.	0,38	6,60
		1-3 positive nodes	891	50,0	26	2,9	905	49,7	14	1,5	1,91		Algorithm converged.	0,99	3,69	0,014		Algorithm converged.	0,000	0,027	1,89		Algorithm converged.	0,99	3,59	0,0531		0,53		Algorithm converged.	0,28	1,01
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	7	1,2	1,19		Algorithm converged.	0,43	3,30	0,002		Algorithm converged.	-0,011	0,015	1,19		Algorithm converged.	0,43	3,25	0,7400		0,84		Algorithm converged.	0,31	2,31
	NASAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	5	0,6	1,84		Algorithm converged.	0,61	5,50	0,005		Algorithm converged.	-0,004	0,013	1,83		Algorithm converged.	0,62	5,43	0,2776		0,55		Algorithm converged.	0,18	1,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014		1,56		Algorithm converged.	0,44	5,49	0,4912		0,64		Algorithm converged.	0,18	2,26
	NASAL MUCOSAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801847 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	NASAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	NASAL POLYPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NASAL SEPTUM ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	NASAL TURBINATE HYPERTROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	NASAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	3	0,3	2,04		Algorithm converged.	0,51	8,18	0,003		Algorithm converged.	-0,003	0,010		2,03		Algorithm converged.	0,51	8,10	0,3151			0,49		Algorithm converged.	0,12	1,96
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013		4,15		Algorithm converged.	0,47	37,03	0,2024			0,24		Algorithm converged.	0,03	2,15
	OROPHARYNGEAL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006		1,02		Algorithm converged.	0,25	4,05	0,9824			0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OROPHARYNGEAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	4	9,5	2,61		Algorithm converged.	0,77	8,92	0,120		Algorithm converged.	-0,023	0,264		2,26		Algorithm converged.	0,78	6,60	0,1339	0,3346	0,44		Algorithm converged.	0,15	1,29
		0 positive nodes, tumor > 1 cm	259	14,5	22	8,5	271	14,9	26	9,6	0,87		Algorithm converged.	0,48	1,59	-0,011		Algorithm converged.	-0,060	0,038		0,89		Algorithm converged.	0,52	1,52	0,6595		1,13		Algorithm converged.	0,66	1,94
		1-3 positive nodes	891	50,0	84	9,4	905	49,7	61	6,7	1,44		Algorithm converged.	1,02	2,03	0,027		Algorithm converged.	0,002	0,052		1,40		Algorithm converged.	1,02	1,92	0,0377		0,71		Algorithm converged.	0,52	0,98
		>= 4 positive nodes	582	32,6	51	8,8	604	33,2	44	7,3	1,22		Algorithm converged.	0,80	1,86	0,015		Algorithm converged.	-0,016	0,046		1,20		Algorithm converged.	0,82	1,77	0,3493		0,83		Algorithm converged.	0,56	1,22
	OROPHARYNGEAL PLAQUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORTHOPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAINFUL RESPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARANASAL SINUS DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	PARANASAL SINUS HYPERSECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGEAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGEAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGEAL SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PLEURAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455			0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PLEURAL THICKENING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PLEURITIC PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	PNEUMOTHORAX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PRODUCTIVE COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	8	0,9	1,53		Algorithm converged.	0,62	3,76	0,005		Algorithm converged.	-0,005	0,014	1,52		Algorithm converged.	0,63	3,71	0,3537		0,66		Algorithm converged.	0,27	1,60
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	7	1,2	0,29		Algorithm converged.	0,06	1,42	-0,008		Algorithm converged.	-0,018	0,002	0,30		Algorithm converged.	0,06	1,42	0,1285		3,37		Algorithm converged.	0,70	16,17
	PULMONARY CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RALES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REFLUX LARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHINALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	RHINITIS ALLERGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	9	3,3	0,81		Algorithm converged.	0,30	2,20	-0,006		Algorithm converged.	-0,035	0,023	0,81		Algorithm converged.	0,31	2,15	0,6781		1,23		Algorithm converged.	0,46	3,25
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	10	1,1	1,33		Algorithm converged.	0,58	3,04	0,004		Algorithm converged.	-0,007	0,014	1,32		Algorithm converged.	0,58	3,00	0,5060		0,76		Algorithm converged.	0,33	1,72
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	9	1,5	0,80		Algorithm converged.	0,30	2,18	-0,003		Algorithm converged.	-0,016	0,010	0,81		Algorithm converged.	0,30	2,15	0,6687		1,24		Algorithm converged.	0,46	3,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHINORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	2	4,8	1,70		Algorithm converged.	0,30	9,78	0,031		Algorithm converged.	-0,067	0,129	1,65		Algorithm converged.	0,32	8,55	0,5528	-	0,61		Algorithm converged.	0,12	3,15
		0 positive nodes, tumor > 1 cm	259	14,5	24	9,3	271	14,9	18	6,6	1,44		Algorithm converged.	0,76	2,71	0,026		Algorithm converged.	-0,020	0,072	1,40		Algorithm converged.	0,78	2,51	0,2662		0,72		Algorithm converged.	0,40	1,29
		1-3 positive nodes	891	50,0	75	8,4	905	49,7	48	5,3	1,64		Algorithm converged.	1,13	2,39	0,031		Algorithm converged.	0,008	0,054	1,59		Algorithm converged.	1,12	2,25	0,0098		0,63		Algorithm converged.	0,44	0,89
		>= 4 positive nodes	582	32,6	39	6,7	604	33,2	25	4,1	1,66		Algorithm converged.	0,99	2,79	0,026		Algorithm converged.	0,000	0,051	1,62		Algorithm converged.	0,99	2,64	0,0535		0,62		Algorithm converged.	0,38	1,01
	SINUS CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SLEEP APNOEA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SNEEZING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	2	0,3	3,14		Algorithm converged.	0,63	15,60	0,007		Algorithm converged.	-0,002	0,016	3,11		Algorithm converged.	0,63	15,36	0,1632		0,32		Algorithm converged.	0,07	1,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPUTUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRIDOR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROAT IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	5	0,6	0,61		Algorithm converged.	0,14	2,55	-0,002		Algorithm converged.	-0,008	0,004	0,61		Algorithm converged.	0,15	2,54	0,4968		1,64		Algorithm converged.	0,39	6,85
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	THROAT TIGHTNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRACHEAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER RESPIRATORY TRACT CONGESTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)											
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	UPPER-AIRWAY COUGH SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	5	1,8	0,62		Algorithm converged.	0,15	2,64	-0,007		Algorithm converged.	-0,028	0,014		0,63		Algorithm converged.	0,15	2,60	0,5209		1,59		Algorithm converged.	0,38	6,60	
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	7	0,8	1,31		Algorithm converged.	0,49	3,53	0,002		Algorithm converged.	-0,006	0,011		1,31		Algorithm converged.	0,49	3,49	0,5948		0,77		Algorithm converged.	0,29	2,05	
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	5	0,8	1,67		Algorithm converged.	0,54	5,13	0,005		Algorithm converged.	-0,006	0,017		1,66		Algorithm converged.	0,55	5,05	0,3712		0,60		Algorithm converged.	0,20	1,83	
	VOCAL CORD INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
	WHEEZING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4	0,76		Algorithm converged.	0,17	3,41	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,39	0,7211		1,31		Algorithm converged.	0,29	5,85
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	43	84,3	42	2,3	32	76,2	1,68		Algorithm converged.	0,60	4,73	0,081		Algorithm converged.	-0,082	0,244	1,11		Algorithm converged.	0,90	1,36	0,3360	0,6010	0,90		Algorithm converged.	0,74	1,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	226	87,3	271	14,9	234	86,3	1,08		Algorithm converged.	0,65	1,79	0,009		Algorithm converged.	-0,049	0,067	1,01		Algorithm converged.	0,95	1,08	0,7565		0,99		Algorithm converged.	0,93	1,06
		1-3 positive nodes	891	50,0	784	88,0	905	49,7	767	84,8	1,32		Algorithm converged.	1,00	1,73	0,032		Algorithm converged.	0,001	0,064	1,04		Algorithm converged.	1,00	1,08	0,0456		0,96		Algorithm converged.	0,93	1,00
		>= 4 positive nodes	582	32,6	513	88,1	604	33,2	501	82,9	1,53		Algorithm converged.	1,10	2,12	0,052		Algorithm converged.	0,012	0,092	1,06		Algorithm converged.	1,01	1,11	0,0110		0,94		Algorithm converged.	0,90	0,99
	ACNE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	1	0,4	6,40		Algorithm converged.	0,77	53,56	0,019		Algorithm converged.	0,000	0,039	6,28		Algorithm converged.	0,76	51,79	0,0880		0,16		Algorithm converged.	0,02	1,31
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	13	1,4	0,70		Algorithm converged.	0,30	1,65	-0,004		Algorithm converged.	-0,014	0,006	0,70		Algorithm converged.	0,30	1,64	0,4140		1,42		Algorithm converged.	0,61	3,31
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	7	1,2	1,04		Algorithm converged.	0,36	2,98	0,000		Algorithm converged.	-0,012	0,013	1,04		Algorithm converged.	0,37	2,94	0,9443		0,96		Algorithm converged.	0,34	2,73
	ACTINIC KERATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821717 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALOPECIA	0 positive nodes, tumor <= 1 cm	51	2,9	32	62,7	42	2,3	24	57,1	1,26		Algorithm converged.	0,55	2,91	0,056		Algorithm converged.	-0,144	0,256	1,10		Algorithm converged.	0,78	1,54	0,5861	0,2237	0,91		Algorithm converged.	0,65	1,28
		0 positive nodes, tumor > 1 cm	259	14,5	172	66,4	271	14,9	199	73,4	0,72		Algorithm converged.	0,49	1,04	-0,070		Algorithm converged.	-0,148	0,008	0,90		Algorithm converged.	0,81	1,01	0,0796		1,11		Algorithm converged.	0,99	1,24
		1-3 positive nodes	891	50,0	613	68,8	905	49,7	603	66,6	1,10		Algorithm converged.	0,91	1,35	0,022		Algorithm converged.	-0,022	0,065	1,03		Algorithm converged.	0,97	1,10	0,3256		0,97		Algorithm converged.	0,91	1,03
		>= 4 positive nodes	582	32,6	389	66,8	604	33,2	403	66,7	1,01		Algorithm converged.	0,79	1,28	0,001		Algorithm converged.	-0,052	0,055	1,00		Algorithm converged.	0,92	1,09	0,9660		1,00		Algorithm converged.	0,92	1,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ALOPECIA AREATA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ALOPECIA TOTALIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ANGIOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLISTER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	2	0,2	4,09		Algorithm converged.	0,87	19,32	0,007		Algorithm converged.	0,000	0,014		4,06		Algorithm converged.	0,87	19,08	0,0757		0,25		Algorithm converged.	0,05	1,16
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	BLOOD BLISTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BUTTERFLY RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLD SWEAT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMAL CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	DERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	8	3,0	2,31		Algorithm converged.	0,98	5,45	0,036		Algorithm converged.	0,000	0,072		2,22		Algorithm converged.	0,98	5,06	0,0570		0,45		Algorithm converged.	0,20	1,02
		1-3 positive nodes	891	50,0	44	4,9	905	49,7	38	4,2	1,19		Algorithm converged.	0,76	1,85	0,007		Algorithm converged.	-0,012	0,027		1,18		Algorithm converged.	0,77	1,80	0,4535		0,85		Algorithm converged.	0,56	1,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	27	4,5	0,68		Algorithm converged.	0,37	1,25	-0,014		Algorithm converged.	-0,035	0,008	0,69		Algorithm converged.	0,39	1,24	0,2175		1,45		Algorithm converged.	0,80	2,60
	DERMATITIS ACNEIFORM	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075	0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26
		0 positive nodes, tumor > 1 cm	259	14,5	16	6,2	271	14,9	4	1,5	4,40		Algorithm converged.	1,45	13,33	0,047		Algorithm converged.	0,014	0,080	4,19		Algorithm converged.	1,42	12,35	0,0095		0,24		Algorithm converged.	0,08	0,71
		1-3 positive nodes	891	50,0	25	2,8	905	49,7	15	1,7	1,71		Algorithm converged.	0,90	3,27	0,011		Algorithm converged.	-0,002	0,025	1,69		Algorithm converged.	0,90	3,19	0,1033		0,59		Algorithm converged.	0,31	1,11
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	12	2,0	1,66		Algorithm converged.	0,80	3,46	0,013		Algorithm converged.	-0,005	0,031	1,64		Algorithm converged.	0,80	3,35	0,1726		0,61		Algorithm converged.	0,30	1,24
	DERMATITIS ALLERGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69
	DERMATITIS ATOPIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS BULLOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATITIS CONTACT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	DERMATITIS DIAPER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DRY SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	6	14,3	0,95		Algorithm converged.	0,29	3,09	-0,006		Algorithm converged.	-0,147	0,136	0,96		Algorithm converged.	0,35	2,64	0,9382	0,4661	1,04		Algorithm converged.	0,38	2,86
		0 positive nodes, tumor > 1 cm	259	14,5	32	12,4	271	14,9	37	13,7	0,89		Algorithm converged.	0,54	1,48	-0,013		Algorithm converged.	-0,070	0,044	0,90		Algorithm converged.	0,58	1,41	0,6574		1,11		Algorithm converged.	0,71	1,72
		1-3 positive nodes	891	50,0	118	13,2	905	49,7	94	10,4	1,32		Algorithm converged.	0,99	1,76	0,029		Algorithm converged.	-0,001	0,058	1,28		Algorithm converged.	0,99	1,64	0,0615		0,78		Algorithm converged.	0,61	1,01
		>= 4 positive nodes	582	32,6	70	12,0	604	33,2	53	8,8	1,42		Algorithm converged.	0,98	2,07	0,033		Algorithm converged.	-0,002	0,067	1,37		Algorithm converged.	0,98	1,92	0,0677		0,73		Algorithm converged.	0,52	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSHIDROTIC ECZEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ECCHYMOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ECZEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	4	1,5	1,85		Algorithm converged.	0,54	6,41	0,012		Algorithm converged.	-0,012	0,037	1,83		Algorithm converged.	0,54	6,18	0,3298		0,55		Algorithm converged.	0,16	1,84
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	8	0,9	2,57		Algorithm converged.	1,13	5,88	0,014		Algorithm converged.	0,002	0,025	2,54		Algorithm converged.	1,12	5,73	0,0250		0,39		Algorithm converged.	0,17	0,89
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	8	1,3	0,78		Algorithm converged.	0,27	2,25	-0,003		Algorithm converged.	-0,015	0,009	0,78		Algorithm converged.	0,27	2,23	0,6407		1,28		Algorithm converged.	0,45	3,68
	ECZEMA ASTEATOTIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE						
	EPIDERMOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	6	14,3	0,95		Algorithm converged.	0,29	3,09	-0,006		Algorithm converged.	-0,147	0,136		0,96		Algorithm converged.	0,35	2,64	0,9382	0,6071	1,04		Algorithm converged.	0,38	2,86	
		0 positive nodes, tumor > 1 cm	259	14,5	19	7,3	271	14,9	18	6,6	1,11		Algorithm converged.	0,57	2,17	0,007		Algorithm converged.	-0,037	0,050		1,10		Algorithm converged.	0,59	2,06	0,7541		0,91		Algorithm converged.	0,49	1,69	
		1-3 positive nodes	891	50,0	108	12,1	905	49,7	86	9,5	1,31		Algorithm converged.	0,97	1,77	0,026		Algorithm converged.	-0,003	0,055		1,28		Algorithm converged.	0,98	1,67	0,0748		0,78		Algorithm converged.	0,60	1,02	
		>= 4 positive nodes	582	32,6	55	9,5	604	33,2	60	9,9	0,95		Algorithm converged.	0,64	1,39	-0,005		Algorithm converged.	-0,039	0,029		0,95		Algorithm converged.	0,67	1,35	0,7785		1,05		Algorithm converged.	0,74	1,49	
	ERYTHEMA MULTIFORME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ERYTHEMA NODOSUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ERYTHROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	EXCESSIVE GRANULATION TISSUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	EXFOLIATIVE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HAIR GROWTH ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HAND DERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HANGNAIL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HIRSUTISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HYPERHIDROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	9	1,0	1,24		Algorithm converged.	0,51	3,02	0,002		Algorithm converged.	-0,007	0,012		1,24		Algorithm converged.	0,52	2,98	0,6285		0,81		Algorithm converged.	0,34	1,93
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005		0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	HYPERKERATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002		0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTRICHOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGROWING NAIL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	4	0,7	1,56		Algorithm converged.	0,44	5,57	0,004		Algorithm converged.	-0,007	0,014	1,56		Algorithm converged.	0,44	5,49	0,4912		0,64		Algorithm converged.	0,18	2,26
	INTERTRIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	ITCHING SCAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LICHEN PLANUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVEDO RETICULARIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00			Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MACULE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MADAROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455			0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,21	5,02	0,9847			0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MECHANICAL URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	MILIARIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506			0,48		Algorithm converged.	0,04	5,30
	NAIL BED BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 46.532527544 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,070		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED TENDERNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	2	4,8	2,17		Algorithm converged.	0,40	11,82	0,050		Algorithm converged.	-0,054	0,154		2,06		Algorithm converged.	0,42	10,08	0,3728	-	0,49		Algorithm converged.	0,10	2,38
		0 positive nodes, tumor > 1 cm	259	14,5	26	10,0	271	14,9	26	9,6	1,05		Algorithm converged.	0,59	1,86	0,004		Algorithm converged.	-0,046	0,055		1,05		Algorithm converged.	0,62	1,75	0,8635		0,96		Algorithm converged.	0,57	1,60
		1-3 positive nodes	891	50,0	67	7,5	905	49,7	64	7,1	1,07		Algorithm converged.	0,75	1,53	0,004		Algorithm converged.	-0,020	0,029		1,06		Algorithm converged.	0,76	1,48	0,7152		0,94		Algorithm converged.	0,68	1,31
		>= 4 positive nodes	582	32,6	38	6,5	604	33,2	49	8,1	0,79		Algorithm converged.	0,51	1,23	-0,016		Algorithm converged.	-0,045	0,014		0,80		Algorithm converged.	0,54	1,21	0,2970		1,24		Algorithm converged.	0,83	1,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL DISCOMFORT	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	NAIL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	1	2,4	7,63		Algorithm converged.	0,91	63,70	0,133		Algorithm converged.	0,023	0,243	6,59		Algorithm converged.	0,86	50,58	0,0699	-	0,15		Algorithm converged.	0,02	1,17
		0 positive nodes, tumor > 1 cm	259	14,5	25	9,7	271	14,9	27	10,0	0,97		Algorithm converged.	0,54	1,71	-0,003		Algorithm converged.	-0,054	0,048	0,97		Algorithm converged.	0,58	1,62	0,9044		1,03		Algorithm converged.	0,62	1,73
		1-3 positive nodes	891	50,0	115	12,9	905	49,7	128	14,1	0,90		Algorithm converged.	0,69	1,18	-0,012		Algorithm converged.	-0,044	0,019	0,91		Algorithm converged.	0,72	1,15	0,4438		1,10		Algorithm converged.	0,87	1,39
		>= 4 positive nodes	582	32,6	73	12,5	604	33,2	48	7,9	1,66		Algorithm converged.	1,13	2,44	0,046		Algorithm converged.	0,011	0,080	1,58		Algorithm converged.	1,12	2,23	0,0097		0,63		Algorithm converged.	0,45	0,90
	NAIL DYSTROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	6	2,2	0,34		Algorithm converged.	0,07	1,72	-0,014		Algorithm converged.	-0,035	0,006	0,35		Algorithm converged.	0,07	1,71	0,1945		2,87		Algorithm converged.	0,58	14,08
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	6	0,7	1,36		Algorithm converged.	0,47	3,93	0,002		Algorithm converged.	-0,006	0,010	1,35		Algorithm converged.	0,47	3,89	0,5730		0,74		Algorithm converged.	0,26	2,12
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005	0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	NAIL GROWTH ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL PIGMENTATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL RIDGING	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	9	3,5	271	14,9	6	2,2	1,59		Algorithm converged.	0,56	4,53	0,013		Algorithm converged.	-0,016	0,041		1,57		Algorithm converged.	0,57	4,35	0,3859		0,64		Algorithm converged.	0,23	1,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	17	1,9	1,14		Algorithm converged.	0,59	2,20	0,003		Algorithm converged.	-0,010	0,016	1,14		Algorithm converged.	0,59	2,17	0,7012		0,88		Algorithm converged.	0,46	1,68
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	11	1,8	1,13		Algorithm converged.	0,50	2,59	0,002		Algorithm converged.	-0,013	0,018	1,13		Algorithm converged.	0,50	2,55	0,7640		0,88		Algorithm converged.	0,39	1,99
	NAIL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029	1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	23	2,5	1,47		Algorithm converged.	0,86	2,53	0,012		Algorithm converged.	-0,004	0,028	1,46		Algorithm converged.	0,86	2,46	0,1592		0,69		Algorithm converged.	0,41	1,16
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	9	1,5	1,63		Algorithm converged.	0,70	3,79	0,009		Algorithm converged.	-0,007	0,025	1,61		Algorithm converged.	0,70	3,70	0,2578		0,62		Algorithm converged.	0,27	1,42
	NEURODERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHT SWEATS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	8	0,9	1,27		Algorithm converged.	0,50	3,24	0,002		Algorithm converged.	-0,007	0,012	1,27		Algorithm converged.	0,50	3,20	0,6130		0,79		Algorithm converged.	0,31	1,99
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	12	2,0	0,51		Algorithm converged.	0,19	1,38	-0,010		Algorithm converged.	-0,023	0,004	0,52		Algorithm converged.	0,20	1,37	0,1865		1,93		Algorithm converged.	0,73	5,10
	NODULAR RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ONYCHALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	8	0,9	1,27		Algorithm converged.	0,50	3,24	0,002		Algorithm converged.	-0,007	0,012	1,27		Algorithm converged.	0,50	3,20	0,6130		0,79		Algorithm converged.	0,31	1,99
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	ONYCHOCLASIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	5	1,8	1,26		Algorithm converged.	0,38	4,19	0,005		Algorithm converged.	-0,020	0,029	1,26		Algorithm converged.	0,39	4,06	0,7041		0,80		Algorithm converged.	0,25	2,58
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	13	1,4	1,17		Algorithm converged.	0,56	2,48	0,002		Algorithm converged.	-0,009	0,014	1,17		Algorithm converged.	0,56	2,45	0,6730		0,85		Algorithm converged.	0,41	1,78
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	7	1,2	0,59		Algorithm converged.	0,17	2,03	-0,005		Algorithm converged.	-0,016	0,006	0,59		Algorithm converged.	0,17	2,02	0,4025		1,69		Algorithm converged.	0,50	5,73
	ONYCHOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048	0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	10	3,7	0,83		Algorithm converged.	0,32	2,14	-0,006		Algorithm converged.	-0,037	0,025	0,84		Algorithm converged.	0,34	2,09	0,7029		1,19		Algorithm converged.	0,48	2,98
		1-3 positive nodes	891	50,0	31	3,5	905	49,7	31	3,4	1,02		Algorithm converged.	0,61	1,69	0,001		Algorithm converged.	-0,016	0,017	1,02		Algorithm converged.	0,62	1,66	0,9502		0,98		Algorithm converged.	0,60	1,61
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	26	4,3	0,51		Algorithm converged.	0,26	1,00	-0,021		Algorithm converged.	-0,041	-0,001	0,52		Algorithm converged.	0,27	1,00	0,0500		1,93		Algorithm converged.	1,00	3,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOMADESIS	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	2	4,8	1,25		Algorithm converged.	0,20	7,85	0,011		Algorithm converged.	-0,080	0,102	1,24		Algorithm converged.	0,22	7,05	0,8121	-	0,81		Algorithm converged.	0,14	4,62
		0 positive nodes, tumor > 1 cm	259	14,5	16	6,2	271	14,9	9	3,3	1,92		Algorithm converged.	0,83	4,42	0,029		Algorithm converged.	-0,008	0,065	1,86		Algorithm converged.	0,84	4,13	0,1277		0,54		Algorithm converged.	0,24	1,19
		1-3 positive nodes	891	50,0	40	4,5	905	49,7	41	4,5	0,99		Algorithm converged.	0,63	1,55	0,000		Algorithm converged.	-0,020	0,019	0,99		Algorithm converged.	0,65	1,52	0,9666		1,01		Algorithm converged.	0,66	1,54
		>= 4 positive nodes	582	32,6	21	3,6	604	33,2	21	3,5	1,04		Algorithm converged.	0,56	1,92	0,001		Algorithm converged.	-0,020	0,022	1,04		Algorithm converged.	0,57	1,88	0,9026		0,96		Algorithm converged.	0,53	1,75
	ONYCHOMALACIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	-	NE		NE	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE		NE	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE		NE	NE	NE
	PAIN OF SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	-	NE		NE	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8	1,16		Algorithm converged.	0,42	3,22	0,001		Algorithm converged.	-0,007	0,010	1,16		Algorithm converged.	0,42	3,19	0,7723		0,86		Algorithm converged.	0,31	2,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	3	0,5	3,50		Algorithm converged.	0,96	12,79	0,012		Algorithm converged.	0,000	0,024		3,46		Algorithm converged.	0,96	12,51	0,0584		0,29		Algorithm converged.	0,08	1,05
	PALMAR ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	4	9,5	1,51		Algorithm converged.	0,41	5,56	0,042		Algorithm converged.	-0,088	0,172		1,44		Algorithm converged.	0,45	4,59	0,5364	0,8681	0,69		Algorithm converged.	0,22	2,21
		0 positive nodes, tumor > 1 cm	259	14,5	31	12,0	271	14,9	25	9,2	1,34		Algorithm converged.	0,77	2,33	0,027		Algorithm converged.	-0,025	0,080		1,30		Algorithm converged.	0,79	2,14	0,3060		0,77		Algorithm converged.	0,47	1,27
		1-3 positive nodes	891	50,0	70	7,9	905	49,7	52	5,7	1,40		Algorithm converged.	0,96	2,03	0,021		Algorithm converged.	-0,002	0,044		1,37		Algorithm converged.	0,97	1,93	0,0770		0,73		Algorithm converged.	0,52	1,03
		>= 4 positive nodes	582	32,6	50	8,6	604	33,2	31	5,1	1,74		Algorithm converged.	1,09	2,76	0,035		Algorithm converged.	0,006	0,063		1,67		Algorithm converged.	1,09	2,58	0,0198		0,60		Algorithm converged.	0,39	0,92
	PAPULE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PEAU D'ORANGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PETECHIAE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007		3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PHOTOSENSITIVITY REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007		1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PIGMENTATION DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	5	1,8	0,41		Algorithm converged.	0,08	2,15	-0,011		Algorithm converged.	-0,030	0,009		0,42		Algorithm converged.	0,08	2,14	0,2952		2,39		Algorithm converged.	0,47	12,21
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008		2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007		0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
	PITYRIASIS ROSEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PLANTAR ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURIGO	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	6	14,3	0,65		Algorithm converged.	0,18	2,31	-0,045		Algorithm converged.	-0,178	0,089	0,69		Algorithm converged.	0,23	2,09	0,5079	0,4519	1,46		Algorithm converged.	0,48	4,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	46	17,8	271	14,9	28	10,3	1,87		Algorithm converged.	1,13	3,10	0,074		Algorithm converged.	0,015	0,133		1,72		Algorithm converged.	1,11	2,66	0,0153		0,58		Algorithm converged.	0,38	0,90	
		1-3 positive nodes	891	50,0	126	14,1	905	49,7	80	8,8	1,70		Algorithm converged.	1,26	2,29	0,053		Algorithm converged.	0,024	0,082		1,60		Algorithm converged.	1,23	2,08	0,0005		0,63		Algorithm converged.	0,48	0,81	
		>= 4 positive nodes	582	32,6	84	14,4	604	33,2	49	8,1	1,91		Algorithm converged.	1,32	2,77	0,063		Algorithm converged.	0,027	0,099		1,78		Algorithm converged.	1,27	2,48	0,0007		0,56		Algorithm converged.	0,40	0,78	
	PSORIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PURPURA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	RASH	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	10	23,8	0,88		Algorithm converged.	0,33	2,33	-0,022		Algorithm converged.	-0,194	0,149	0,91		Algorithm converged.	0,43	1,92	0,7969	0,3538	1,10		Algorithm converged.	0,52	2,34
		0 positive nodes, tumor > 1 cm	259	14,5	68	26,3	271	14,9	63	23,2	1,18		Algorithm converged.	0,79	1,74	0,030		Algorithm converged.	-0,043	0,104	1,13		Algorithm converged.	0,84	1,52	0,4227		0,89		Algorithm converged.	0,66	1,19
		1-3 positive nodes	891	50,0	231	25,9	905	49,7	189	20,9	1,33		Algorithm converged.	1,06	1,65	0,050		Algorithm converged.	0,011	0,090	1,24		Algorithm converged.	1,05	1,47	0,0119		0,81		Algorithm converged.	0,68	0,95
		>= 4 positive nodes	582	32,6	151	25,9	604	33,2	106	17,5	1,65		Algorithm converged.	1,24	2,18	0,084		Algorithm converged.	0,037	0,131	1,48		Algorithm converged.	1,19	1,84	0,0005		0,68		Algorithm converged.	0,54	0,84
	RASH ERYTHEMATOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	RASH FOLLICULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	6	0,7	1,19		Algorithm converged.	0,40	3,54	0,001		Algorithm converged.	-0,007	0,009		1,18		Algorithm converged.	0,40	3,51	0,7595		0,84		Algorithm converged.	0,28	2,50
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010		1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	RASH MACULO-PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	14	5,2	0,74		Algorithm converged.	0,32	1,69	-0,013		Algorithm converged.	-0,048	0,022		0,75		Algorithm converged.	0,34	1,65	0,4720		1,34		Algorithm converged.	0,61	2,96
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	21	2,3	1,62		Algorithm converged.	0,93	2,82	0,014		Algorithm converged.	-0,002	0,030		1,60		Algorithm converged.	0,93	2,74	0,0892		0,63		Algorithm converged.	0,37	1,07
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	9	1,5	1,87		Algorithm converged.	0,82	4,26	0,013		Algorithm converged.	-0,004	0,029		1,84		Algorithm converged.	0,82	4,14	0,1377		0,54		Algorithm converged.	0,24	1,22
	RASH PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006		1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	RASH PRURITIC	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016		0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	8	0,9	0,38		Algorithm converged.	0,10	1,43	-0,005		Algorithm converged.	-0,013	0,002		0,38		Algorithm converged.	0,10	1,43	0,1529		2,63		Algorithm converged.	0,70	9,86
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013		1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41
	RASH VESICULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ROSACEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SCAB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801 64 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCAR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	5	0,8	1,67		Algorithm converged.	0,54	5,13	0,005		Algorithm converged.	-0,006	0,017	1,66		Algorithm converged.	0,55	5,05	0,3712		0,60		Algorithm converged.	0,20	1,83
	SEBORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEBORRHOEIC DERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SENSITIVE SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ATROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	SKIN BURNING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN DEPIGMENTATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	7	0,8	0,43		Algorithm converged.	0,11	1,68	-0,004		Algorithm converged.	-0,011	0,002	0,44		Algorithm converged.	0,11	1,68	0,2270		2,30		Algorithm converged.	0,60	8,86
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	SKIN DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011	1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	5	0,8	1,25		Algorithm converged.	0,38	4,11	0,002		Algorithm converged.	-0,009	0,013	1,25		Algorithm converged.	0,38	4,06	0,7158		0,80		Algorithm converged.	0,25	2,62
	SKIN EROSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	6	2,2	0,69		Algorithm converged.	0,19	2,48	-0,007		Algorithm converged.	-0,030	0,016	0,70		Algorithm converged.	0,20	2,44	0,5734		1,43		Algorithm converged.	0,41	5,02
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	11	1,2	1,49		Algorithm converged.	0,69	3,22	0,006		Algorithm converged.	-0,005	0,017	1,48		Algorithm converged.	0,69	3,17	0,3155		0,68		Algorithm converged.	0,32	1,45
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	11	1,8	0,94		Algorithm converged.	0,40	2,24	-0,001		Algorithm converged.	-0,016	0,014	0,94		Algorithm converged.	0,40	2,20	0,8931		1,06		Algorithm converged.	0,45	2,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN FISSURES	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8	0,40		Algorithm converged.	0,03	4,57	-0,028		Algorithm converged.	-0,103	0,047		0,41		Algorithm converged.	0,04	4,38	0,4622	-	2,43		Algorithm converged.	0,23	25,86
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	2	0,7	2,11		Algorithm converged.	0,38	11,62	0,008		Algorithm converged.	-0,010	0,026		2,09		Algorithm converged.	0,39	11,33	0,3914		0,48		Algorithm converged.	0,09	2,59
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	13	1,4	1,02		Algorithm converged.	0,47	2,20	0,000		Algorithm converged.	-0,011	0,011		1,02		Algorithm converged.	0,47	2,18	0,9681		0,98		Algorithm converged.	0,46	2,11
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	7	1,2	1,19		Algorithm converged.	0,43	3,30	0,002		Algorithm converged.	-0,011	0,015		1,19		Algorithm converged.	0,43	3,25	0,7400		0,84		Algorithm converged.	0,31	2,31
	SKIN HYPERPIGMENTATION	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133992 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	8	3,0	1,32		Algorithm converged.	0,51	3,40	0,009		Algorithm converged.	-0,022	0,040		1,31		Algorithm converged.	0,52	3,26	0,5649		0,76		Algorithm converged.	0,31	1,91
		1-3 positive nodes	891	50,0	45	5,1	905	49,7	30	3,3	1,55		Algorithm converged.	0,97	2,49	0,017		Algorithm converged.	-0,001	0,036		1,52		Algorithm converged.	0,97	2,40	0,0683		0,66		Algorithm converged.	0,42	1,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	22	3,8	604	33,2	31	5,1	0,73		Algorithm converged.	0,42	1,27	-0,014		Algorithm converged.	-0,037	0,010	0,74		Algorithm converged.	0,43	1,26	0,2620		1,36		Algorithm converged.	0,80	2,32	
	SKIN HYPERTROPHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SKIN HYPOPIGMENTATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INDURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	4	0,4	2,04		Algorithm converged.	0,61	6,80	0,005		Algorithm converged.	-0,003	0,012	2,03		Algorithm converged.	0,61	6,72	0,2457		0,49		Algorithm converged.	0,15	1,63
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN LESION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	3	0,3	2,72		Algorithm converged.	0,72	10,30	0,006		Algorithm converged.	-0,002	0,013	2,71		Algorithm converged.	0,72	10,18	0,1401		0,37		Algorithm converged.	0,10	1,39
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48
	SKIN MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN ODOUR ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SKIN OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN PLAQUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	SKIN SWELLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN TIGHTNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	7	0,8	1,46		Algorithm converged.	0,55	3,84	0,003		Algorithm converged.	-0,005	0,012	1,45		Algorithm converged.	0,55	3,80	0,4479		0,69		Algorithm converged.	0,26	1,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	3	0,5	2,79		Algorithm converged.	0,74	10,58	0,009		Algorithm converged.	-0,002	0,020		2,77		Algorithm converged.	0,74	10,38	0,1313		0,36		Algorithm converged.	0,10	1,36
	SKIN ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133902 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	6	0,7	1,53		Algorithm converged.	0,54	4,31	0,003		Algorithm converged.	-0,005	0,012		1,52		Algorithm converged.	0,54	4,26	0,4225		0,66		Algorithm converged.	0,23	1,84
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	SKIN WRINKLING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			NE	NE
	SPIDER NAEVUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TELANGIECTASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	TOXIC SKIN ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UMBILICAL ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	7	2,6	0,74		Algorithm converged.	0,23	2,37	-0,007		Algorithm converged.	-0,032	0,019		0,75		Algorithm converged.	0,24	2,33	0,6151			1,34		Algorithm converged.	0,43	4,16
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	14	1,5	0,65		Algorithm converged.	0,28	1,51	-0,005		Algorithm converged.	-0,016	0,005		0,65		Algorithm converged.	0,28	1,50	0,3155			1,53		Algorithm converged.	0,67	3,52
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	8	1,3	1,84		Algorithm converged.	0,76	4,41	0,011		Algorithm converged.	-0,005	0,026		1,82		Algorithm converged.	0,77	4,30	0,1744			0,55		Algorithm converged.	0,23	1,30
	URTICARIA CONTACT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URTICARIA PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	XERODERMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
SOCIAL CIRCUMSTANCE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	INADEQUATE DIET	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENOPAUSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
SURGICAL AND MEDICAL PROCEDURE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002	0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	4	0,7	1,04		Algorithm converged.	0,26	4,17	0,000		Algorithm converged.	-0,009	0,010	1,04		Algorithm converged.	0,26	4,13	0,9580		0,96		Algorithm converged.	0,24	3,83
	ASTRINGENT THERAPY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20	
	BREAST RECONSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	BREAST TUMOUR EXCISION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CENTRAL VENOUS CATHETER REMOVAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	CENTRAL VENOUS CATHETERISATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DENTAL CARE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HOSPITALISATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUS OPERATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH RESTORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	18	35,3	42	2,3	14	33,3	1,09		Algorithm converged.	0,46	2,58	0,020		Algorithm converged.	-0,174	0,213	1,06		Algorithm converged.	0,60	1,87	0,8433	0,2393	0,94		Algorithm converged.	0,54	1,66
		0 positive nodes, tumor > 1 cm	259	14,5	73	28,2	271	14,9	89	32,8	0,80		Algorithm converged.	0,55	1,16	-0,047		Algorithm converged.	-0,125	0,032	0,86		Algorithm converged.	0,66	1,11	0,2462		1,17		Algorithm converged.	0,90	1,51
		1-3 positive nodes	891	50,0	352	39,5	905	49,7	347	38,3	1,05		Algorithm converged.	0,87	1,27	0,012		Algorithm converged.	-0,033	0,057	1,03		Algorithm converged.	0,92	1,16	0,6131		0,97		Algorithm converged.	0,86	1,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	187	32,1	604	33,2	226	37,4	0,79		Algorithm converged.	0,62	1,01	-0,053		Algorithm converged.	-0,107	0,001		0,86		Algorithm converged.	0,73	1,00	0,0569		1,16		Algorithm converged.	1,00	1,36	
	ANGIOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ANGIOSCLEROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AORTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARTERIOSCLEROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AXILLARY VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO															PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOOD PRESSURE FLUCTUATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BLOODY DISCHARGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CIRCULATORY COLLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DEEP VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	5	0,6	0,61		Algorithm converged.	0,14	2,55	-0,002		Algorithm converged.	-0,008	0,004	0,61		Algorithm converged.	0,15	2,54	0,4968		1,64		Algorithm converged.	0,39	6,85	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82	
	DRY GANGRENE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24	
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	1	0,2	5,23		Algorithm converged.	0,61	44,86	0,007		Algorithm converged.	-0,001	0,015	5,19		Algorithm converged.	0,61	44,28	0,1323		0,19		Algorithm converged.	0,02	1,64
	EMBOLISM VENOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FLUSHING	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	8	3,0	0,65		Algorithm converged.	0,21	2,00	-0,010		Algorithm converged.	-0,036	0,016	0,65		Algorithm converged.	0,22	1,97	0,4510		1,53		Algorithm converged.	0,51	4,61
		1-3 positive nodes	891	50,0	45	5,1	905	49,7	35	3,9	1,32		Algorithm converged.	0,84	2,08	0,012		Algorithm converged.	-0,007	0,031	1,31		Algorithm converged.	0,85	2,01	0,2258		0,77		Algorithm converged.	0,50	1,18
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	15	2,5	0,48		Algorithm converged.	0,19	1,18	-0,013		Algorithm converged.	-0,028	0,002	0,48		Algorithm converged.	0,20	1,18	0,1103		2,06		Algorithm converged.	0,85	5,03
	HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	HOT FLUSH	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	4	9,5	1,77		Algorithm converged.	0,49	6,34	0,062		Algorithm converged.	-0,072	0,195	1,65		Algorithm converged.	0,53	5,09	0,3862	0,1794	0,61		Algorithm converged.	0,20	1,88
		0 positive nodes, tumor > 1 cm	259	14,5	38	14,7	271	14,9	38	14,0	1,05		Algorithm converged.	0,65	1,71	0,006		Algorithm converged.	-0,053	0,066	1,05		Algorithm converged.	0,69	1,59	0,8311		0,96		Algorithm converged.	0,63	1,45
		1-3 positive nodes	891	50,0	191	21,4	905	49,7	184	20,3	1,07		Algorithm converged.	0,85	1,34	0,011		Algorithm converged.	-0,027	0,049	1,05		Algorithm converged.	0,88	1,26	0,5646		0,95		Algorithm converged.	0,79	1,14
		>= 4 positive nodes	582	32,6	96	16,5	604	33,2	127	21,0	0,74		Algorithm converged.	0,55	1,00	-0,045		Algorithm converged.	-0,090	-0,001	0,78		Algorithm converged.	0,62	1,00	0,0469		1,27		Algorithm converged.	1,00	1,62
	HYPERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	1	2,4	3,49		Algorithm converged.	0,37	32,48	0,055		Algorithm converged.	-0,032	0,142	3,29		Algorithm converged.	0,38	28,36	0,2778	-	0,30		Algorithm converged.	0,04	2,61						
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	18	6,6	0,74		Algorithm converged.	0,36	1,55	-0,016		Algorithm converged.	-0,056	0,024	0,76		Algorithm converged.	0,38	1,51	0,4280		1,32		Algorithm converged.	0,66	2,65						
		1-3 positive nodes	891	50,0	39	4,4	905	49,7	49	5,4	0,80		Algorithm converged.	0,52	1,23	-0,010		Algorithm converged.	-0,030	0,010	0,81		Algorithm converged.	0,54	1,22	0,3097		1,24		Algorithm converged.	0,82	1,86						
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	29	4,8	0,63		Algorithm converged.	0,35	1,15	-0,017		Algorithm converged.	-0,039	0,005	0,64		Algorithm converged.	0,36	1,15	0,1352		1,55		Algorithm converged.	0,87	2,76						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSIVE CRISIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	3	7,1	0,00		Algorithm converged.	0,00	NE	-0,092	*	WARNING: The relative Hessian convergence criterion of 4.6935579102 is greater than the limit of 0.0001. The convergence is questionable.	-0,384	0,199	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	4	1,5	1,58		Algorithm converged.	0,44	5,68	0,008		Algorithm converged.	-0,015	0,032	1,57		Algorithm converged.	0,45	5,50	0,4810		0,64		Algorithm converged.	0,18	2,23
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	18	2,0	1,02		Algorithm converged.	0,53	1,97	0,000		Algorithm converged.	-0,013	0,013	1,02		Algorithm converged.	0,53	1,94	0,9623		0,98		Algorithm converged.	0,52	1,88
		>= 4 positive nodes	582	32,6	16	2,7	604	33,2	5	0,8	3,39		Algorithm converged.	1,23	9,31	0,019		Algorithm converged.	0,004	0,034	3,32		Algorithm converged.	1,22	9,01	0,0184		0,30		Algorithm converged.	0,11	0,82
	INFERIOR VENA CAVA DILATATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INTERNAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	JUGULAR VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	5	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9998		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	4	9,5	0,59		Algorithm converged.	0,13	2,82	-0,036		Algorithm converged.	-0,146	0,073	0,62		Algorithm converged.	0,15	2,61	0,5120	-	1,62		Algorithm converged.	0,38	6,83
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	6	2,2	1,41		Algorithm converged.	0,48	4,11	0,009		Algorithm converged.	-0,019	0,036	1,40		Algorithm converged.	0,49	3,97	0,5322		0,72		Algorithm converged.	0,25	2,04
		1-3 positive nodes	891	50,0	64	7,2	905	49,7	78	8,6	0,82		Algorithm converged.	0,58	1,16	-0,014		Algorithm converged.	-0,039	0,011	0,83		Algorithm converged.	0,61	1,14	0,2604		1,20		Algorithm converged.	0,87	1,65
		>= 4 positive nodes	582	32,6	49	8,4	604	33,2	67	11,1	0,74		Algorithm converged.	0,50	1,09	-0,027		Algorithm converged.	-0,060	0,007	0,76		Algorithm converged.	0,53	1,08	0,1229		1,32		Algorithm converged.	0,93	1,87
	LYMPHORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOSTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ORTHOSTATIC HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PALLOR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL COLDNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL VASCULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	PERIPHERAL VENOUS DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20	
	PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	7	2,6	0,15		Algorithm converged.	0,02	1,20	-0,022		Algorithm converged.	-0,042	-0,002		0,15		Algorithm converged.	0,02	1,21	0,0745		6,69		Algorithm converged.	0,83	54,00	
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	18	2,0	1,02		Algorithm converged.	0,53	1,97	0,000		Algorithm converged.	-0,013	0,013		1,02		Algorithm converged.	0,53	1,94	0,9623		0,98		Algorithm converged.	0,52	1,88	
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	11	1,8	1,04		Algorithm converged.	0,45	2,41	0,001		Algorithm converged.	-0,015	0,016		1,04		Algorithm converged.	0,45	2,38	0,9300		0,96		Algorithm converged.	0,42	2,21	
	PHLEBITIS SUPERFICIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PREHYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 42.426716 29 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPERFICIAL VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUPERIOR VENA CAVA OCCLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUPERIOR VENA CAVA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
	THROMBOSED VARICOSE VEIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,003		Algorithm converged.	-0,010	0,004	0,58		Algorithm converged.	0,17	1,98	0,3841		1,72		Algorithm converged.	0,51	5,87
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	6	1,0	0,34		Algorithm converged.	0,07	1,71	-0,006		Algorithm converged.	-0,016	0,003	0,35		Algorithm converged.	0,07	1,71	0,1924		2,89		Algorithm converged.	0,59	14,26
	VARICOSE VEIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	VASCULAR RUPTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8	1,16		Algorithm converged.	0,42	3,22	0,001		Algorithm converged.	-0,007	0,010	1,16		Algorithm converged.	0,42	3,19	0,7723		0,86		Algorithm converged.	0,31	2,37
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69
	VASODILATATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VEIN DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	VENOUS THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS LIMB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82

Test for interaction based on RR (Log-binomial regression).

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_ANYAE_S1.xls
05MAY2022 13:13

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	580	32,5	1822	100,0	539	29,6	1,15		Algorithm converged.	1,00	1,32	0,029		Algorithm converged.	-0,001	0,060	1,10		Algorithm converged.	1,00	1,21	0,0561		0,91		Algorithm converged.	0,83	1,00
	AGRANULOCYTOSIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ANAEMIA	n/a	1783	100,0	120	6,7	1822	100,0	86	4,7	1,46		Algorithm converged.	1,10	1,94	0,020		Algorithm converged.	0,005	0,035	1,43		Algorithm converged.	1,09	1,87	0,0098		0,70		Algorithm converged.	0,54	0,92
	BLOOD DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BONE MARROW FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	FEBRILE NEUTROPENIA	n/a	1783	100,0	212	11,9	1822	100,0	190	10,4	1,16		Algorithm converged.	0,94	1,43	0,015		Algorithm converged.	-0,006	0,035	1,14		Algorithm converged.	0,95	1,37	0,1636		0,88		Algorithm converged.	0,73	1,05
	GRANULOCYTOPENIA	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	HAEMATOTOXICITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOLYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	IRON DEFICIENCY ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	LEUKOCYTOSIS	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEUKOPENIA	n/a	1783	100,0	79	4,4	1822	100,0	97	5,3	0,82		Algorithm converged.	0,61	1,12	-0,009		Algorithm converged.	-0,023	0,005	0,83		Algorithm converged.	0,62	1,11	0,2142		1,20		Algorithm converged.	0,90	1,61
	LYMPHOPENIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYELOSUPPRESSION	n/a	1783	100,0	6	0,3	1822	100,0	8	0,4	0,77		Algorithm converged.	0,27	2,21	-0,001		Algorithm converged.	-0,005	0,003	0,77		Algorithm converged.	0,27	2,20	0,6216		1,30		Algorithm converged.	0,45	3,75
	NEUTROPENIA	n/a	1783	100,0	300	16,8	1822	100,0	284	15,6	1,10		Algorithm converged.	0,92	1,31	0,012		Algorithm converged.	-0,012	0,036	1,08		Algorithm converged.	0,93	1,25	0,3132		0,93		Algorithm converged.	0,80	1,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	n/a	1783	100,0	17	1,0	1822	100,0	23	1,3	0,75		Algorithm converged.	0,40	1,41	-0,003		Algorithm converged.	-0,010	0,004	0,76		Algorithm converged.	0,40	1,41	0,3777		1,32		Algorithm converged.	0,71	2,47
CARDIAC DISORDER	-Total	n/a	1783	100,0	28	1,6	1822	100,0	24	1,3	1,20		Algorithm converged.	0,69	2,07	0,003		Algorithm converged.	-0,005	0,010	1,19		Algorithm converged.	0,69	2,05	0,5244		0,84		Algorithm converged.	0,49	1,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGINA PECTORIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	ATRIAL FIBRILLATION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRADYCARDIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIAC FAILURE	n/a	1783	100,0	14	0,8	1822	100,0	7	0,4	2,05		Algorithm converged.	0,83	5,10	0,004		Algorithm converged.	-0,001	0,009	2,04		Algorithm converged.	0,83	5,05	0,1216		0,49		Algorithm converged.	0,20	1,21

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC FAILURE CONGESTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CARDIAC VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSIVE CARDIOMYOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERICARDIAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STRESS CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TACHYCARDIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA PAROXYSMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRICUSPID VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	APLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYLORIC STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	EXTERNAL EAR INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOACUSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERTIGO	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
ENDOCRINE DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	GOITRE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTHYROIDISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EYE DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	CATARACT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY EYE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LACRIMATION INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RETINAL DETACHMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RETINAL VASCULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS FLOATERS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	268	15,0	1822	100,0	169	9,3	1,73		Algorithm converged.	1,41	2,12	0,058		Algorithm converged.	0,036	0,079	1,62		Algorithm converged.	1,35	1,94	<.0001		0,62		Algorithm converged.	0,51	0,74
	ABDOMINAL PAIN	n/a	1783	100,0	9	0,5	1822	100,0	9	0,5	1,02		Algorithm converged.	0,40	2,58	0,000		Algorithm converged.	-0,004	0,005	1,02		Algorithm converged.	0,41	2,57	0,9633		0,98		Algorithm converged.	0,39	2,46
	ABDOMINAL PAIN UPPER	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISSURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL FISTULA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APHTHOUS ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COLITIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS ISCHAEMIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONSTIPATION	n/a	1783	100,0	9	0,5	1822	100,0	6	0,3	1,54		Algorithm converged.	0,55	4,32	0,002		Algorithm converged.	-0,002	0,006	1,53		Algorithm converged.	0,55	4,30	0,4168		0,65		Algorithm converged.	0,23	1,83
	DENTAL CARIES	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	n/a	1783	100,0	168	9,4	1822	100,0	71	3,9	2,57		Algorithm converged.	1,93	3,41	0,055		Algorithm converged.	0,039	0,071	2,42		Algorithm converged.	1,85	3,17	<.0001		0,41		Algorithm converged.	0,32	0,54
	DRY MOUTH	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DUODENAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUODENAL ULCER HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTERITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ENTEROCOLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL TOXICITY	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GLOSSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHOIDS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INGUINAL HERNIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTESTINAL ISCHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTUSSUSCEPTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOOSE TOOTH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MOUTH ULCERATION	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAUSEA	n/a	1783	100,0	36	2,0	1822	100,0	43	2,4	0,85		Algorithm converged.	0,54	1,33	-0,003		Algorithm converged.	-0,013	0,006	0,86		Algorithm converged.	0,55	1,33	0,4849		1,17		Algorithm converged.	0,75	1,81
	ORAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL INTESTINAL OBSTRUCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	n/a	1783	100,0	38	2,1	1822	100,0	18	1,0	2,18		Algorithm converged.	1,24	3,84	0,011		Algorithm converged.	0,003	0,020	2,16		Algorithm converged.	1,24	3,77	0,0068		0,46		Algorithm converged.	0,27	0,81
	SUBILEUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH DEVELOPMENT DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	VOMITING	n/a	1783	100,0	30	1,7	1822	100,0	33	1,8	0,93		Algorithm converged.	0,56	1,53	-0,001		Algorithm converged.	-0,010	0,007	0,93		Algorithm converged.	0,57	1,52	0,7683		1,08		Algorithm converged.	0,66	1,76
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	126	7,1	1822	100,0	123	6,8	1,05		Algorithm converged.	0,81	1,36	0,003		Algorithm converged.	-0,013	0,020	1,05		Algorithm converged.	0,82	1,33	0,7084		0,96		Algorithm converged.	0,75	1,21
	ASTHENIA	n/a	1783	100,0	22	1,2	1822	100,0	34	1,9	0,66		Algorithm converged.	0,38	1,13	-0,006		Algorithm converged.	-0,014	0,002	0,66		Algorithm converged.	0,39	1,13	0,1277		1,51		Algorithm converged.	0,89	2,58

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	CHILLS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTRAVASATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FACIAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FATIGUE	n/a	1783	100,0	69	3,9	1822	100,0	49	2,7	1,46		Algorithm converged.	1,00	2,11	0,012		Algorithm converged.	0,000	0,023	1,44		Algorithm converged.	1,00	2,06	0,0477		0,69		Algorithm converged.	0,48	1,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	GENERALISED OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INFLUENZA LIKE ILLNESS	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION SITE EXTRAVASATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE EXTRAVASATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MALAISE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUCOSAL DRYNESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MUCOSAL INFLAMMATION	n/a	1783	100,0	23	1,3	1822	100,0	12	0,7	1,97		Algorithm converged.	0,98	3,97	0,006		Algorithm converged.	0,000	0,013	1,96		Algorithm converged.	0,98	3,92	0,0580		0,51		Algorithm converged.	0,25	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OEDEMA PERIPHERAL	n/a	1783	100,0	0	0,0	1822	100,0	5	0,3	0,00		Algorithm converged.	0,00	NE	-0,003	*	WARNING: The relative Hessian convergence criterion of 51.704547935 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAIN	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYREXIA	n/a	1783	100,0	8	0,4	1822	100,0	12	0,7	0,68		Algorithm converged.	0,28	1,67	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,28	1,66	0,3991		1,47		Algorithm converged.	0,60	3,58
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	CHOLANGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG-INDUCED LIVER INJURY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FUNCTION ABNORMAL	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	HYPERTRANSAMINASAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	14	0,8	1822	100,0	16	0,9	0,89		Algorithm converged.	0,43	1,84	-0,001		Algorithm converged.	-0,007	0,005	0,89		Algorithm converged.	0,44	1,83	0,7588		1,12		Algorithm converged.	0,55	2,28
	ANAPHYLACTIC REACTION	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERSENSITIVITY	n/a	1783	100,0	6	0,3	1822	100,0	8	0,4	0,77		Algorithm converged.	0,27	2,21	-0,001		Algorithm converged.	-0,005	0,003	0,77		Algorithm converged.	0,27	2,20	0,6216		1,30		Algorithm converged.	0,45	3,75
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	125	7,0	1822	100,0	124	6,8	1,03		Algorithm converged.	0,80	1,34	0,002		Algorithm converged.	-0,015	0,019	1,03		Algorithm converged.	0,81	1,31	0,8083		0,97		Algorithm converged.	0,76	1,23
	ABDOMINAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABSCESS LIMB	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE HEPATITIS B	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS PERFORATED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BACTERIAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BRONCHITIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	CATHETER SITE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CELLULITIS	n/a	1783	100,0	13	0,7	1822	100,0	11	0,6	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,004	0,007	1,21		Algorithm converged.	0,54	2,69	0,6440		0,83		Algorithm converged.	0,37	1,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CLOSTRIDIUM DIFFICILE INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	CYSTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE RELATED INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	DIVERTICULITIS INTESTINAL PERFORATED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOCARDITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ENTEROCOLITIS INFECTIOUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHERICHIA INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FURUNCLE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROENTERITIS	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01
	GASTROENTERITIS VIRAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	GROIN ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS B REACTIVATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES OPHTHALMIC	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES SIMPLEX	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES VIRUS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES ZOSTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTED LYMPHOCELE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOCALISED INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHANGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81
	MUCOSAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASOPHARYNGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	n/a	1783	100,0	8	0,4	1822	100,0	3	0,2	2,73		Algorithm converged.	0,72	10,32	0,003		Algorithm converged.	-0,001	0,006	2,72		Algorithm converged.	0,72	10,25	0,1382		0,37		Algorithm converged.	0,10	1,38
	ORAL CANDIDIASIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL FUNGAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OROPHARYNGITIS FUNGAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC INFLAMMATORY DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIODONTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PERITONSILLAR ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PHARYNGITIS BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHLEBITIS INFECTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	n/a	1783	100,0	11	0,6	1822	100,0	15	0,8	0,75		Algorithm converged.	0,34	1,63	-0,002		Algorithm converged.	-0,008	0,003	0,75		Algorithm converged.	0,35	1,63	0,4658		1,33		Algorithm converged.	0,61	2,90
	PNEUMONIA ASPIRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMONIA PNEUMOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POST PROCEDURAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PSEUDOMONAS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SALPINGO-OOPHORITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPSIS	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12
	SEPTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERRATIA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SINUSITIS	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	7	0,4	0,44		Algorithm converged.	0,11	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2310		2,28		Algorithm converged.	0,59	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STAPHYLOCOCCAL SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509 423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STREPTOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TOOTH ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	URINARY TRACT INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	10	0,5	0,41		Algorithm converged.	0,13	1,30	-0,003		Algorithm converged.	-0,007	0,001	0,41		Algorithm converged.	0,13	1,30	0,1299		2,45		Algorithm converged.	0,77	7,79
	URINARY TRACT INFECTION ENTEROCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION PSEUDOMONAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	VAGINAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	VASCULAR DEVICE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL CANDIDIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	WOUND INFECTION STAPHYLOCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	30	1,7	1822	100,0	30	1,6	1,02		Algorithm converged.	0,61	1,70	0,000		Algorithm converged.	-0,008	0,009	1,02		Algorithm converged.	0,62	1,69	0,9327		0,98		Algorithm converged.	0,59	1,62
	ACCIDENTAL OVERDOSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FALL	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEMORAL NECK FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FOOT FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GRAFT THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAND FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HUMERUS FRACTURE	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	ILIUM FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFUSION RELATED REACTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIGAMENT SPRAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER LIMB FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOCONIOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RADIATION INJURY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	RADIATION SKIN INJURY	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIUS FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.37850919 4 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ROAD TRAFFIC ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEROMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SPINAL COMPRESSION FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THERMAL BURN	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TIBIA FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOXICITY TO VARIOUS AGENTS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ULNA FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND COMPLICATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND DEHISCENCE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	WOUND HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WRIST FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INVESTIGATION	-Total	n/a	1783	100,0	294	16,5	1822	100,0	297	16,3	1,01		Algorithm converged.	0,85	1,21	0,002		Algorithm converged.	-0,022	0,026	1,01		Algorithm converged.	0,87	1,17	0,8787		0,99		Algorithm converged.	0,85	1,15
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	15	0,8	1822	100,0	17	0,9	0,90		Algorithm converged.	0,45	1,81	-0,001		Algorithm converged.	-0,007	0,005	0,90		Algorithm converged.	0,45	1,80	0,7691		1,11		Algorithm converged.	0,56	2,21
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	8	0,4	1822	100,0	9	0,5	0,91		Algorithm converged.	0,35	2,36	0,000		Algorithm converged.	-0,005	0,004	0,91		Algorithm converged.	0,35	2,35	0,8428		1,10		Algorithm converged.	0,43	2,85
	BLOOD ALKALINE PHOSPHATASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CHOLESTEROL INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BLOOD CREATININE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD GLUCOSE FLUCTUATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD MAGNESIUM INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD POTASSIUM DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD PRESSURE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD TRIGLYCERIDES INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	C-REACTIVE PROTEIN INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EJECTION FRACTION DECREASED	n/a	1783	100,0	29	1,6	1822	100,0	30	1,6	0,99		Algorithm converged.	0,59	1,65	0,000		Algorithm converged.	-0,008	0,008	0,99		Algorithm converged.	0,60	1,64	0,9621		1,01		Algorithm converged.	0,61	1,68
	GAMMA-GLUTAMYLTRANSFERASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	7	0,4	0,29		Algorithm converged.	0,06	1,40	-0,003		Algorithm converged.	-0,006	0,001	0,29		Algorithm converged.	0,06	1,40	0,1243		3,43		Algorithm converged.	0,71	16,46
	GLOMERULAR FILTRATION RATE DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOGLOBIN DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC ENZYME INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIPASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTE COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84
	LYMPHOCYTE COUNT INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	180	10,1	1822	100,0	187	10,3	0,98		Algorithm converged.	0,79	1,22	-0,002		Algorithm converged.	-0,021	0,018	0,98		Algorithm converged.	0,81	1,19	0,8675		1,02		Algorithm converged.	0,84	1,23
	NEUTROPHIL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	n/a	1783	100,0	19	1,1	1822	100,0	10	0,5	1,95		Algorithm converged.	0,90	4,21	0,005		Algorithm converged.	-0,001	0,011	1,94		Algorithm converged.	0,91	4,16	0,0883		0,52		Algorithm converged.	0,24	1,10
	TRANSAMINASES INCREASED	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN T INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINE OUTPUT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WEIGHT DECREASED	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	WEIGHT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	WHITE BLOOD CELL COUNT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	92	5,2	1822	100,0	65	3,6	1,47		Algorithm converged.	1,06	2,03	0,016		Algorithm converged.	0,003	0,029	1,45		Algorithm converged.	1,06	1,97	0,0200		0,69		Algorithm converged.	0,51	0,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	89	5,0	1822	100,0	47	2,6	1,98		Algorithm converged.	1,38	2,84	0,024		Algorithm converged.	0,012	0,037	1,94		Algorithm converged.	1,37	2,74	0,0002		0,52		Algorithm converged.	0,37	0,73
	DECREASED APPETITE	n/a	1783	100,0	15	0,8	1822	100,0	8	0,4	1,92		Algorithm converged.	0,81	4,55	0,004		Algorithm converged.	-0,001	0,009	1,92		Algorithm converged.	0,81	4,51	0,1363		0,52		Algorithm converged.	0,22	1,23
	DEHYDRATION	n/a	1783	100,0	17	1,0	1822	100,0	3	0,2	5,84		Algorithm converged.	1,71	19,95	0,008		Algorithm converged.	0,003	0,013	5,79		Algorithm converged.	1,70	19,72	0,0050		0,17		Algorithm converged.	0,05	0,59
	DIABETES MELLITUS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETIC METABOLIC DECOMPENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	FAILURE TO THRIVE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FLUID RETENTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	n/a	1783	100,0	9	0,5	1822	100,0	7	0,4	1,32		Algorithm converged.	0,49	3,54	0,001		Algorithm converged.	-0,003	0,006	1,31		Algorithm converged.	0,49	3,52	0,5873		0,76		Algorithm converged.	0,28	2,04
	HYPERKALAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERMAGNESAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTRIGLYCERIDAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	n/a	1783	100,0	33	1,9	1822	100,0	14	0,8	2,44		Algorithm converged.	1,30	4,57	0,011		Algorithm converged.	0,003	0,018	2,41		Algorithm converged.	1,29	4,49	0,0056		0,42		Algorithm converged.	0,22	0,77
	HYPOMAGNESAEMIA	n/a	1783	100,0	17	1,0	1822	100,0	1	<0.1	17,53		Algorithm converged.	2,33	131,86	0,009		Algorithm converged.	0,004	0,014	17,37		Algorithm converged.	2,31	130,40	0,0055		0,06		Algorithm converged.	0,01	0,43
	HYPONATRAEMIA	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	8	0,4	1822	100,0	3	0,2	2,73		Algorithm converged.	0,72	10,32	0,003		Algorithm converged.	-0,001	0,006	2,72		Algorithm converged.	0,72	10,25	0,1382		0,37		Algorithm converged.	0,10	1,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPROTEINAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOVOLAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OBESITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TETANY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TUMOUR LYSIS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	33	1,9	1822	100,0	55	3,0	0,61		Algorithm converged.	0,39	0,94	-0,012		Algorithm converged.	-0,022	-0,002	0,61		Algorithm converged.	0,40	0,94	0,0246		1,63		Algorithm converged.	1,06	2,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTHRALGIA	n/a	1783	100,0	13	0,7	1822	100,0	22	1,2	0,60		Algorithm converged.	0,30	1,20	-0,005		Algorithm converged.	-0,011	0,002	0,60		Algorithm converged.	0,31	1,19	0,1474		1,66		Algorithm converged.	0,84	3,28
	BACK PAIN	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	BONE PAIN	n/a	1783	100,0	2	0,1	1822	100,0	7	0,4	0,29		Algorithm converged.	0,06	1,40	-0,003		Algorithm converged.	-0,006	0,001	0,29		Algorithm converged.	0,06	1,40	0,1243		3,43		Algorithm converged.	0,71	16,46
	INTERVERTEBRAL DISC PROTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULAR WEAKNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL CHEST PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL PAIN	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5902		1,37		Algorithm converged.	0,44	4,31

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYALGIA	n/a	1783	100,0	13	0,7	1822	100,0	21	1,2	0,63		Algorithm converged.	0,31	1,26	-0,004		Algorithm converged.	-0,011	0,002	0,63		Algorithm converged.	0,32	1,26	0,1924		1,58		Algorithm converged.	0,79	3,15
	PAIN IN EXTREMITY	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	RHEUMATOID ARTHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SJOGREN'S SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SPINAL OSTEOARTHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL STENOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	8	0,4	1822	100,0	10	0,5	0,82		Algorithm converged.	0,32	2,07	-0,001		Algorithm converged.	-0,006	0,004	0,82		Algorithm converged.	0,32	2,07	0,6702		1,22		Algorithm converged.	0,48	3,09
	ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADENOCARCINOMA PANCREAS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST CANCER IN SITU	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONOCLONAL GAMMOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PAPILLARY THYROID CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL CELL LUNG CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SQUAMOUS CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE LEIOMYOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	79	4,4	1822	100,0	59	3,2	1,39		Algorithm converged.	0,98	1,95	0,012		Algorithm converged.	-0,001	0,024		1,37		Algorithm converged.	0,98	1,90	0,0633		0,73		Algorithm converged.	0,52	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARPAL TUNNEL SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBRAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CERVICAL RADICULOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	n/a	1783	100,0	0	0,0	1822	100,0	5	0,3	0,00		Algorithm converged.	0,00	NE	-0,003	*	WARNING: The relative Hessian convergence criterion of 51.704547935 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHAGE INTRACRANIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEADACHE	n/a	1783	100,0	3	0,2	1822	100,0	7	0,4	0,44		Algorithm converged.	0,11	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2310		2,28		Algorithm converged.	0,59	8,82
	INTERCOSTAL NEURALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	LETHARGY	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	MIGRAINE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUROPATHY PERIPHERAL	n/a	1783	100,0	9	0,5	1822	100,0	12	0,7	0,77		Algorithm converged.	0,32	1,82	-0,002		Algorithm converged.	-0,006	0,003	0,77		Algorithm converged.	0,32	1,81	0,5451		1,30		Algorithm converged.	0,55	3,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARAESTHESIA	n/a	1783	100,0	8	0,4	1822	100,0	2	0,1	4,10		Algorithm converged.	0,87	19,34	0,003		Algorithm converged.	0,000	0,007	4,09		Algorithm converged.	0,87	19,22	0,0747		0,24		Algorithm converged.	0,05	1,15
	PERIPHERAL MOTOR NEUROPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PERIPHERAL SENSORY NEUROPATHY	n/a	1783	100,0	12	0,7	1822	100,0	9	0,5	1,36		Algorithm converged.	0,57	3,25	0,002		Algorithm converged.	-0,003	0,007	1,36		Algorithm converged.	0,58	3,23	0,4818		0,73		Algorithm converged.	0,31	1,74
	POLYNEUROPATHY	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	PRESYNCOPE	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	SCIATICA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	n/a	1783	100,0	19	1,1	1822	100,0	13	0,7	1,50		Algorithm converged.	0,74	3,04	0,004		Algorithm converged.	-0,003	0,010	1,49		Algorithm converged.	0,74	3,01	0,2630		0,67		Algorithm converged.	0,33	1,35
	THALAMIC INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRANSIENT ISCHAEMIC ATTACK	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PRODUCT ISSUE	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	17	1,0	1822	100,0	11	0,6	1,58		Algorithm converged.	0,74	3,39	0,003		Algorithm converged.	-0,002	0,009	1,58		Algorithm converged.	0,74	3,36	0,2359		0,63		Algorithm converged.	0,30	1,35
	ANXIETY	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DEPRESSION	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMOTIONAL DISTRESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INSOMNIA	n/a	1783	100,0	7	0,4	1822	100,0	2	0,1	3,59		Algorithm converged.	0,74	17,29	0,003		Algorithm converged.	0,000	0,006	3,58		Algorithm converged.	0,74	17,19	0,1116		0,28		Algorithm converged.	0,06	1,34
	MAJOR DEPRESSION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENTAL DISORDER	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	REACTIVE PSYCHOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.37850895 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDAL IDEATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDE ATTEMPT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	8	0,4	1822	100,0	9	0,5	0,91		Algorithm converged.	0,35	2,36	0,000		Algorithm converged.	-0,005	0,004	0,91		Algorithm converged.	0,35	2,35	0,8428		1,10		Algorithm converged.	0,43	2,85
	ACUTE KIDNEY INJURY	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLADDER PROLAPSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSURIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEPHROLITHIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL IMPAIRMENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETERIC OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	n/a	1783	100,0	32	1,8	1822	100,0	37	2,0	0,88		Algorithm converged.	0,55	1,42	-0,002		Algorithm converged.	-0,011	0,007		0,88		Algorithm converged.	0,55	1,41	0,6054		1,13		Algorithm converged.	0,71	1,81
	AMENORRHOEA	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003		0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST HAEMATOMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAVY MENSTRUAL BLEEDING	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUATION IRREGULAR	n/a	1783	100,0	19	1,1	1822	100,0	22	1,2	0,88		Algorithm converged.	0,48	1,63	-0,001		Algorithm converged.	-0,008	0,005	0,88		Algorithm converged.	0,48	1,62	0,6882		1,13		Algorithm converged.	0,62	2,09
	PREMATURE MENOPAUSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL DRYNESS	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	VULVOVAGINAL PRURITUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	24	1,3	1822	100,0	23	1,3	1,07		Algorithm converged.	0,60	1,90	0,001		Algorithm converged.	-0,007	0,008	1,07		Algorithm converged.	0,60	1,88	0,8247		0,94		Algorithm converged.	0,53	1,66
	ACUTE RESPIRATORY DISTRESS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APHONIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ASTHMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATELECTASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRONCHOSPASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARRH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	COUGH	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHONIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSPNOEA	n/a	1783	100,0	6	0,3	1822	100,0	10	0,5	0,61		Algorithm converged.	0,22	1,69	-0,002		Algorithm converged.	-0,006	0,002	0,61		Algorithm converged.	0,22	1,68	0,3425		1,63		Algorithm converged.	0,59	4,48
	EPISTAXIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERSTITIAL LUNG DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LUNG CONSOLIDATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONITIS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	PNEUMOTHORAX	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PULMONARY EMBOLISM	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	PULMONARY FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RHINORRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHEEZING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	63	3,5	1822	100,0	36	2,0	1,82		Algorithm converged.	1,20	2,75	0,016		Algorithm converged.	0,005	0,026	1,79		Algorithm converged.	1,19	2,68	0,0048		0,56		Algorithm converged.	0,37	0,84
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALOPECIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANGIOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLISTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	DERMATITIS ACNEIFORM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRY SKIN	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ERYTHEMA	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXFOLIATIVE RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGROWING NAIL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL DISCOLOURATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL TOXICITY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	NIGHT SWEATS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOCLASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOLYSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ONYCHOMADESIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	n/a	1783	100,0	20	1,1	1822	100,0	6	0,3	3,43		Algorithm converged.	1,38	8,57	0,008		Algorithm converged.	0,002	0,013	3,41		Algorithm converged.	1,37	8,46	0,0083		0,29		Algorithm converged.	0,12	0,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHOTOSENSITIVITY REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURITUS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	PSORIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	RASH MACULAR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH MACULO-PAPULAR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCAR PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN EXFOLIATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN IRRITATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN LESION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN TOXICITY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	SKIN ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXIC EPIDERMAL NECROLYSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOXIC SKIN ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	URTICARIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST RECONSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST TUMOUR EXCISION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	n/a	1783	100,0	40	2,2	1822	100,0	57	3,1	0,71		Algorithm converged.	0,47	1,07	-0,009		Algorithm converged.	-0,019	0,002	0,72		Algorithm converged.	0,48	1,07	0,1023		1,39		Algorithm converged.	0,94	2,08
	AXILLARY VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEEP VEIN THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	EMBOLISM	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HOT FLUSH	n/a	1783	100,0	4	0,2	1822	100,0	8	0,4	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,15	1,69	0,2721		1,96		Algorithm converged.	0,59	6,49
	HYPERTENSION	n/a	1783	100,0	23	1,3	1822	100,0	33	1,8	0,71		Algorithm converged.	0,41	1,21	-0,005		Algorithm converged.	-0,013	0,003	0,71		Algorithm converged.	0,42	1,21	0,2081		1,40		Algorithm converged.	0,83	2,38
	HYPOTENSION	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JUGULAR VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ORTHOSTATIC HYPOTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SUPERIOR VENA CAVA OCCLUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOPHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	VENOUS THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR345_S1.xls
05MAY2022 16:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	503	32,2	1601	87,9	465	29,0	1,16		Algorithm converged.	1,00	1,35	0,031		Algorithm converged.	-0,001	0,063	1,11		Algorithm converged.	1,00	1,23	0,0573	0,7094	0,90		Algorithm converged.	0,81	1,00
		>= 65	219	12,3	77	35,2	221	12,1	74	33,5	1,08		Algorithm converged.	0,73	1,60	0,017		Algorithm converged.	-0,072	0,105	1,05		Algorithm converged.	0,81	1,36	0,7113		0,95		Algorithm converged.	0,74	1,23
	AGRANULOCYTOSIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAEMIA	< 65	1564	87,7	94	6,0	1601	87,9	64	4,0	1,54		Algorithm converged.	1,11	2,13	0,020		Algorithm converged.	0,005	0,035	1,50		Algorithm converged.	1,10	2,05	0,0099	0,4645	0,67		Algorithm converged.	0,49	0,91
		>= 65	219	12,3	26	11,9	221	12,1	22	10,0	1,22		Algorithm converged.	0,67	2,22	0,019		Algorithm converged.	-0,039	0,077	1,19		Algorithm converged.	0,70	2,04	0,5196		0,84		Algorithm converged.	0,49	1,43
	BLOOD DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BONE MARROW FAILURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	7	0,4	1601	87,9	5	0,3	1,44		Algorithm converged.	0,45	4,53	0,001		Algorithm converged.	-0,003	0,006	1,43		Algorithm converged.	0,46	4,51	0,5381	-	0,70		Algorithm converged.	0,22	2,19
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	181	11,6	1601	87,9	157	9,8	1,20		Algorithm converged.	0,96	1,51	0,018		Algorithm converged.	-0,004	0,039	1,18		Algorithm converged.	0,96	1,44	0,1082	0,3868	0,85		Algorithm converged.	0,69	1,04
		>= 65	219	12,3	31	14,2	221	12,1	33	14,9	0,94		Algorithm converged.	0,55	1,60	-0,008		Algorithm converged.	-0,074	0,058	0,95		Algorithm converged.	0,60	1,49	0,8173		1,05		Algorithm converged.	0,67	1,66
	GRANULOCYTOPENIA	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOTOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LEUKOCYTOSIS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	LEUKOPENIA	< 65	1564	87,7	73	4,7	1601	87,9	82	5,1	0,91		Algorithm converged.	0,66	1,25	-0,005		Algorithm converged.	-0,020	0,010	0,91		Algorithm converged.	0,67	1,24	0,5540	0,0889	1,10		Algorithm converged.	0,81	1,49
		>= 65	219	12,3	6	2,7	221	12,1	15	6,8	0,39		Algorithm converged.	0,15	1,02	-0,040		Algorithm converged.	-0,080	-0,001	0,40		Algorithm converged.	0,16	1,02	0,0554		2,48		Algorithm converged.	0,98	6,27
	LYMPHOPENIA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	< 65	1564	87,7	6	0,4	1601	87,9	8	0,5	0,77		Algorithm converged.	0,27	2,22	-0,001		Algorithm converged.	-0,006	0,003	0,77		Algorithm converged.	0,27	2,21	0,6238	-	1,30		Algorithm converged.	0,45	3,75
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	< 65	1564	87,7	262	16,8	1601	87,9	251	15,7	1,08		Algorithm converged.	0,90	1,31	0,011		Algorithm converged.	-0,015	0,036	1,07		Algorithm converged.	0,91	1,25	0,4124	0,7180	0,94		Algorithm converged.	0,80	1,10
		>= 65	219	12,3	38	17,4	221	12,1	33	14,9	1,20		Algorithm converged.	0,72	1,99	0,024		Algorithm converged.	-0,045	0,093	1,16		Algorithm converged.	0,76	1,78	0,4909		0,86		Algorithm converged.	0,56	1,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	< 65	1564	87,7	16	1,0	1601	87,9	16	1,0	1,02		Algorithm converged.	0,51	2,05	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,51	2,04	0,9470	-	0,98		Algorithm converged.	0,49	1,95
		>= 65	219	12,3	1	0,5	221	12,1	7	3,2	0,14		Algorithm converged.	0,02	1,15	-0,027		Algorithm converged.	-0,052	-0,002	0,14		Algorithm converged.	0,02	1,16	0,0689		6,94		Algorithm converged.	0,86	55,91
CARDIAC DISORDER	-Total	< 65	1564	87,7	20	1,3	1601	87,9	17	1,1	1,21		Algorithm converged.	0,63	2,31	0,002		Algorithm converged.	-0,005	0,010	1,20		Algorithm converged.	0,63	2,29	0,5708	0,9430	0,83		Algorithm converged.	0,44	1,58
		>= 65	219	12,3	8	3,7	221	12,1	7	3,2	1,16		Algorithm converged.	0,41	3,25	0,005		Algorithm converged.	-0,029	0,039	1,15		Algorithm converged.	0,43	3,13	0,7792		0,87		Algorithm converged.	0,32	2,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGINA PECTORIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ATRIAL FIBRILLATION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ATRIAL THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	< 65	1564	87,7	9	0,6	1601	87,9	5	0,3	1,85		Algorithm converged.	0,62	5,52	0,003		Algorithm converged.	-0,002	0,007	1,84		Algorithm converged.	0,62	5,49	0,2722	-	0,54		Algorithm converged.	0,18	1,62
		>= 65	219	12,3	5	2,3	221	12,1	2	0,9	2,56		Algorithm converged.	0,49	13,33	0,014		Algorithm converged.	-0,010	0,037	2,52		Algorithm converged.	0,49	12,87	0,2656		0,40		Algorithm converged.	0,08	2,02
	CARDIAC FAILURE CONGESTIVE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MITRAL VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERICARDIAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRESS CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA PAROXYSMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICUSPID VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTERNAL EAR INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOACUSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VERTIGO	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VESTIBULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	GOITRE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTHYROIDISM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARACT	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRY EYE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RETINAL DETACHMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL VASCULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS FLOATERS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	215	13,7	1601	87,9	138	8,6	1,69		Algorithm converged.	1,35	2,12	0,051		Algorithm converged.	0,029	0,073	1,59		Algorithm converged.	1,30	1,95	<.0001	0,7311	0,63		Algorithm converged.	0,51	0,77
		>= 65	219	12,3	53	24,2	221	12,1	31	14,0	1,96		Algorithm converged.	1,20	3,19	0,102		Algorithm converged.	0,029	0,175	1,73		Algorithm converged.	1,15	2,58	0,0078		0,58		Algorithm converged.	0,39	0,87
	ABDOMINAL PAIN	< 65	1564	87,7	8	0,5	1601	87,9	9	0,6	0,91		Algorithm converged.	0,35	2,36	-0,001		Algorithm converged.	-0,006	0,005	0,91		Algorithm converged.	0,35	2,35	0,8456	-	1,10		Algorithm converged.	0,43	2,84
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ABDOMINAL PAIN UPPER	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL FISSURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISTULA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHTHOUS ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS ISCHAEMIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DENTAL CARIES	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	< 65	1564	87,7	131	8,4	1601	87,9	53	3,3	2,67		Algorithm converged.	1,93	3,70	0,051		Algorithm converged.	0,034	0,067	2,53		Algorithm converged.	1,85	3,45	<.0001	0,5303	0,40		Algorithm converged.	0,29	0,54
		>= 65	219	12,3	37	16,9	221	12,1	18	8,1	2,29		Algorithm converged.	1,26	4,17	0,088		Algorithm converged.	0,026	0,149	2,07		Algorithm converged.	1,22	3,53	0,0071		0,48		Algorithm converged.	0,28	0,82
	DRY MOUTH	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTERITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GLOSSITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHOIDS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOOSE TOOTH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MOUTH ULCERATION	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAUSEA	< 65	1564	87,7	30	1,9	1601	87,9	38	2,4	0,80		Algorithm converged.	0,50	1,30	-0,005		Algorithm converged.	-0,015	0,006	0,81		Algorithm converged.	0,50	1,30	0,3780	0,5296	1,24		Algorithm converged.	0,77	1,99
		>= 65	219	12,3	6	2,7	221	12,1	5	2,3	1,22		Algorithm converged.	0,37	4,05	0,005		Algorithm converged.	-0,024	0,034	1,21		Algorithm converged.	0,38	3,91	0,7489		0,83		Algorithm converged.	0,26	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	< 65	1564	87,7	30	1,9	1601	87,9	15	0,9	2,07		Algorithm converged.	1,11	3,86	0,010		Algorithm converged.	0,002	0,018	2,05		Algorithm converged.	1,11	3,79	0,0226	0,7082	0,49		Algorithm converged.	0,26	0,90
		>= 65	219	12,3	8	3,7	221	12,1	3	1,4	2,76		Algorithm converged.	0,72	10,53	0,023		Algorithm converged.	-0,006	0,052	2,69		Algorithm converged.	0,72	10,01	0,1397		0,37		Algorithm converged.	0,10	1,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBILEUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VOMITING	< 65	1564	87,7	25	1,6	1601	87,9	28	1,7	0,91		Algorithm converged.	0,53	1,57	-0,002		Algorithm converged.	-0,010	0,007	0,91		Algorithm converged.	0,54	1,56	0,7417	0,8846	1,09		Algorithm converged.	0,64	1,87
		>= 65	219	12,3	5	2,3	221	12,1	5	2,3	1,01		Algorithm converged.	0,29	3,54	0,000		Algorithm converged.	-0,028	0,028	1,01		Algorithm converged.	0,30	3,44	0,9884		0,99		Algorithm converged.	0,29	3,37
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	97	6,2	1601	87,9	95	5,9	1,05		Algorithm converged.	0,78	1,40	0,003		Algorithm converged.	-0,014	0,019	1,05		Algorithm converged.	0,79	1,37	0,7520	0,9999	0,96		Algorithm converged.	0,73	1,26
		>= 65	219	12,3	29	13,2	221	12,1	28	12,7	1,05		Algorithm converged.	0,60	1,84	0,006		Algorithm converged.	-0,057	0,068	1,05		Algorithm converged.	0,64	1,70	0,8581		0,96		Algorithm converged.	0,59	1,55
	ASTHENIA	< 65	1564	87,7	12	0,8	1601	87,9	22	1,4	0,55		Algorithm converged.	0,27	1,13	-0,006		Algorithm converged.	-0,013	0,001	0,56		Algorithm converged.	0,28	1,12	0,1027	0,4559	1,79		Algorithm converged.	0,89	3,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	10	4,6	221	12,1	12	5,4	0,83		Algorithm converged.	0,35	1,97	-0,009		Algorithm converged.	-0,049	0,032	0,84		Algorithm converged.	0,37	1,91	0,6781		1,19		Algorithm converged.	0,52	2,69
	AXILLARY PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHILLS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FACIAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	< 65	1564	87,7	51	3,3	1601	87,9	40	2,5	1,32		Algorithm converged.	0,86	2,00	0,008		Algorithm converged.	-0,004	0,019	1,31		Algorithm converged.	0,87	1,96	0,2008	0,3240	0,77		Algorithm converged.	0,51	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	18	8,2	221	12,1	9	4,1	2,11		Algorithm converged.	0,93	4,80	0,041		Algorithm converged.	-0,003	0,086	2,02		Algorithm converged.	0,93	4,39	0,0769		0,50		Algorithm converged.	0,23	1,08
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	GENERALISED OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA LIKE ILLNESS	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION SITE EXTRAVASATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MASS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DRYNESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	< 65	1564	87,7	20	1,3	1601	87,9	9	0,6	2,29		Algorithm converged.	1,04	5,05	0,007		Algorithm converged.	0,001	0,014	2,27		Algorithm converged.	1,04	4,98	0,0398	-	0,44		Algorithm converged.	0,20	0,96
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	< 65	1564	87,7	0	0,0	1601	87,9	5	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYREXIA	< 65	1564	87,7	8	0,5	1601	87,9	10	0,6	0,82		Algorithm converged.	0,32	2,08	-0,001		Algorithm converged.	-0,006	0,004	0,82		Algorithm converged.	0,32	2,07	0,6728	-	1,22		Algorithm converged.	0,48	3,09
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLANGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLELITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FUNCTION ABNORMAL	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRANSAMINASAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	14	0,9	1601	87,9	14	0,9	1,02		Algorithm converged.	0,49	2,15	0,000		Algorithm converged.	-0,006	0,007	1,02		Algorithm converged.	0,49	2,14	0,9505	-	0,98		Algorithm converged.	0,47	2,04
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAPHYLACTIC REACTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1	5,13		Algorithm converged.	0,60	43,97	0,003		Algorithm converged.	0,000	0,006	5,12		Algorithm converged.	0,60	43,76	0,1359	-	0,20		Algorithm converged.	0,02	1,67
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HYPERSENSITIVITY	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	100	6,4	1601	87,9	106	6,6	0,96		Algorithm converged.	0,73	1,28	-0,002		Algorithm converged.	-0,019	0,015	0,97		Algorithm converged.	0,74	1,26	0,7958	0,2465	1,04		Algorithm converged.	0,80	1,35
		>= 65	219	12,3	25	11,4	221	12,1	18	8,1	1,45		Algorithm converged.	0,77	2,75	0,033		Algorithm converged.	-0,023	0,088	1,40		Algorithm converged.	0,79	2,49	0,2509		0,71		Algorithm converged.	0,40	1,27
	ABDOMINAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABSCESS LIMB	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	APPENDICITIS PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	< 65	1564	87,7	10	0,6	1601	87,9	11	0,7	0,93		Algorithm converged.	0,39	2,20	0,000		Algorithm converged.	-0,006	0,005	0,93		Algorithm converged.	0,40	2,18	0,8688	-	1,07		Algorithm converged.	0,46	2,52
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	CONJUNCTIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	CYSTITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001		0,41		Algorithm converged.	0,08	2,11	0,2854	-		2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DIVERTICULITIS INTESTINAL PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ENDOCARDITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ENTEROCOLITIS INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FURUNCLE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	GASTROENTERITIS VIRAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GROIN ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES OPHTHALMIC	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES VIRUS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	INFECTED SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	LARYNGITIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOCALISED INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000			>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LYMPHANGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUCOSAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL CANDIDIASIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARONYCHIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PELVIC INFLAMMATORY DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIODONTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERITONSILLAR ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	< 65	1564	87,7	7	0,4	1601	87,9	13	0,8	0,55		Algorithm converged.	0,22	1,38	-0,004		Algorithm converged.	-0,009	0,002	0,55		Algorithm converged.	0,22	1,38	0,2026	-	1,81		Algorithm converged.	0,73	4,54
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA ASPIRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA PNEUMOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE WOUND INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMONAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS ACUTE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SALPINGO-OOPHORITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SEPSIS	< 65	1564	87,7	3	0,2	1601	87,9	7	0,4	0,44		Algorithm converged.	0,11	1,70	-0,002		Algorithm converged.	-0,006	0,001		0,44		Algorithm converged.	0,11	1,69	0,2319	-		2,28		Algorithm converged.	0,59	8,80
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024		1,51		Algorithm converged.	0,26	8,97	0,6479			0,66		Algorithm converged.	0,11	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERRATIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUSITIS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONSILLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	9	0,6	0,34		Algorithm converged.	0,09	1,26	-0,004		Algorithm converged.	-0,008	0,001	0,34		Algorithm converged.	0,09	1,26	0,1063	-	2,93		Algorithm converged.	0,79	10,81
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION ENTEROCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VIRAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAL ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WOUND INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION STAPHYLOCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	27	1,7	1601	87,9	27	1,7	1,02		Algorithm converged.	0,60	1,75	0,000		Algorithm converged.	-0,009	0,009		1,02		Algorithm converged.	0,60	1,74	0,9309	-	0,98		Algorithm converged.	0,58	1,66
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022		1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACCIDENTAL OVERDOSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FALL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEMORAL NECK FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOOT FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRAFT THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ILIUM FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED REACTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LIGAMENT SPRAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER LIMB FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX TRAUMATIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RADIATION SKIN INJURY	< 65	1564	87,7	5	0,3	1601	87,9	7	0,4	0,73		Algorithm converged.	0,23	2,31	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5922	-	1,37		Algorithm converged.	0,43	4,30
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RADIUS FRACTURE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECALL PHENOMENON	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	SPINAL COMPRESSION FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
	THERMAL BURN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TIBIA FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULNA FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR ACCESS COMPLICATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND COMPLICATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND DEHISCENCE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
INVESTIGATION	-Total	< 65	1564	87,7	254	16,2	1601	87,9	258	16,1	1,01		Algorithm converged.	0,84	1,22	0,001		Algorithm converged.	-0,024	0,027	1,01		Algorithm converged.	0,86	1,18	0,9236	0,9033	0,99		Algorithm converged.	0,85	1,16
		>= 65	219	12,3	40	18,3	221	12,1	39	17,6	1,04		Algorithm converged.	0,64	1,70	0,006		Algorithm converged.	-0,066	0,078	1,04		Algorithm converged.	0,69	1,54	0,8660		0,97		Algorithm converged.	0,65	1,44
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	14	0,9	1601	87,9	15	0,9	0,96		Algorithm converged.	0,46	1,99	0,000		Algorithm converged.	-0,007	0,006	0,96		Algorithm converged.	0,46	1,97	0,9019	-	1,05		Algorithm converged.	0,51	2,16
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	8	0,5	1601	87,9	9	0,6	0,91		Algorithm converged.	0,35	2,36	-0,001		Algorithm converged.	-0,006	0,005	0,91		Algorithm converged.	0,35	2,35	0,8456	-	1,10		Algorithm converged.	0,43	2,84
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BLOOD CREATININE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE FLUCTUATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD POTASSIUM DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	C-REACTIVE PROTEIN INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	EJECTION FRACTION DECREASED	< 65	1564	87,7	25	1,6	1601	87,9	23	1,4	1,11		Algorithm converged.	0,63	1,97	0,002		Algorithm converged.	-0,007	0,010		1,11		Algorithm converged.	0,63	1,95	0,7096	0,3278		0,90		Algorithm converged.	0,51	1,58
		>= 65	219	12,3	4	1,8	221	12,1	7	3,2	0,57		Algorithm converged.	0,16	1,97	-0,013		Algorithm converged.	-0,043	0,016		0,58		Algorithm converged.	0,17	1,94	0,3742			1,73		Algorithm converged.	0,51	5,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	6	0,4	0,17		Algorithm converged.	0,02	1,41	-0,003		Algorithm converged.	-0,006	0,000	0,17		Algorithm converged.	0,02	1,42	0,1014	-	5,86		Algorithm converged.	0,71	48,63
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	GLOMERULAR FILTRATION RATE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOGLOBIN DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC ENZYME INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	5	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOCYTE COUNT INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	160	10,2	1601	87,9	168	10,5	0,97		Algorithm converged.	0,77	1,22	-0,003		Algorithm converged.	-0,024	0,019	0,97		Algorithm converged.	0,79	1,20	0,8081	0,7906	1,03		Algorithm converged.	0,84	1,26
		>= 65	219	12,3	20	9,1	221	12,1	19	8,6	1,07		Algorithm converged.	0,55	2,06	0,005		Algorithm converged.	-0,048	0,058	1,06		Algorithm converged.	0,58	1,93	0,8435		0,94		Algorithm converged.	0,52	1,71

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	< 65	1564	87,7	14	0,9	1601	87,9	9	0,6	1,60		Algorithm converged.	0,69	3,70	0,003		Algorithm converged.	-0,003	0,009	1,59		Algorithm converged.	0,69	3,67	0,2745	-	0,63		Algorithm converged.	0,27	1,45
		>= 65	219	12,3	5	2,3	221	12,1	1	0,5	5,14		Algorithm converged.	0,60	44,36	0,018		Algorithm converged.	-0,003	0,040	5,05		Algorithm converged.	0,59	42,84	0,1380		0,20		Algorithm converged.	0,02	1,68
	TRANSAMINASES INCREASED	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN T INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINE OUTPUT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	WEIGHT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	76	4,9	1601	87,9	58	3,6	1,36		Algorithm converged.	0,96	1,93	0,012		Algorithm converged.	-0,002	0,026	1,34		Algorithm converged.	0,96	1,87	0,0853	0,2417	0,75		Algorithm converged.	0,53	1,04
		>= 65	219	12,3	16	7,3	221	12,1	7	3,2	2,41		Algorithm converged.	0,97	5,98	0,041		Algorithm converged.	0,000	0,083	2,31		Algorithm converged.	0,97	5,50	0,0592		0,43		Algorithm converged.	0,18	1,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	58	3,7	1601	87,9	36	2,2	1,67		Algorithm converged.	1,10	2,55	0,015		Algorithm converged.	0,003	0,026	1,65		Algorithm converged.	1,09	2,49	0,0168	0,1611	0,61		Algorithm converged.	0,40	0,91
		>= 65	219	12,3	31	14,2	221	12,1	11	5,0	3,15		Algorithm converged.	1,54	6,44	0,092		Algorithm converged.	0,037	0,146	2,84		Algorithm converged.	1,47	5,51	0,0020		0,35		Algorithm converged.	0,18	0,68
	DECREASED APPETITE	< 65	1564	87,7	8	0,5	1601	87,9	6	0,4	1,37		Algorithm converged.	0,47	3,95	0,001		Algorithm converged.	-0,003	0,006	1,36		Algorithm converged.	0,47	3,92	0,5638	-	0,73		Algorithm converged.	0,25	2,11
		>= 65	219	12,3	7	3,2	221	12,1	2	0,9	3,62		Algorithm converged.	0,74	17,60	0,023		Algorithm converged.	-0,004	0,049	3,53		Algorithm converged.	0,74	16,81	0,1130		0,28		Algorithm converged.	0,06	1,35
	DEHYDRATION	< 65	1564	87,7	11	0,7	1601	87,9	3	0,2	3,77		Algorithm converged.	1,05	13,55	0,005		Algorithm converged.	0,001	0,010	3,75		Algorithm converged.	1,05	13,43	0,0420	-	0,27		Algorithm converged.	0,07	0,95
		>= 65	219	12,3	6	2,7	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETES MELLITUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DIABETIC METABOLIC DECOMPENSATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROLYTE IMBALANCE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FAILURE TO THRIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86
	HYPERKALAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERMAGNESAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRIGLYCERIDAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	< 65	1564	87,7	23	1,5	1601	87,9	10	0,6	2,37		Algorithm converged.	1,13	5,01	0,008		Algorithm converged.	0,001	0,016	2,35		Algorithm converged.	1,12	4,93	0,0232	0,9207	0,42		Algorithm converged.	0,20	0,89
		>= 65	219	12,3	10	4,6	221	12,1	4	1,8	2,60		Algorithm converged.	0,80	8,41	0,028		Algorithm converged.	-0,005	0,060	2,52		Algorithm converged.	0,80	7,92	0,1130		0,40		Algorithm converged.	0,13	1,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOMAGNESAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963341 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	13	5,9	221	12,1	1	0,5	13,88		Algorithm converged.	1,80	107,07	0,055		Algorithm converged.	0,022	0,087	13,12		Algorithm converged.	1,73	99,42	0,0127		0,08		Algorithm converged.	0,01	0,58
	HYPONATRAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPROTEINAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOVOLAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OBESITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TETANY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TUMOUR LYSIS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	< 65	1564	87,7	27	1,7	1601	87,9	48	3,0	0,57		Algorithm converged.	0,35	0,92	-0,013		Algorithm converged.	-0,023	-0,002	0,58		Algorithm converged.	0,36	0,92	0,0203	0,4983	1,74		Algorithm converged.	1,09	2,77
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	ARTHRALGIA	< 65	1564	87,7	11	0,7	1601	87,9	19	1,2	0,59		Algorithm converged.	0,28	1,24	-0,005		Algorithm converged.	-0,012	0,002	0,59		Algorithm converged.	0,28	1,24	0,1654	-	1,69		Algorithm converged.	0,81	3,53
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	BACK PAIN	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE PAIN	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERVERTEBRAL DISC PROTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULAR WEAKNESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL CHEST PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYALGIA	< 65	1564	87,7	10	0,6	1601	87,9	20	1,2	0,51		Algorithm converged.	0,24	1,09	-0,006		Algorithm converged.	-0,013	0,001	0,51		Algorithm converged.	0,24	1,09	0,0824	-	1,95		Algorithm converged.	0,92	4,16
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAIN IN EXTREMITY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	RHEUMATOID ARTHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SJOGREN'S SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL OSTEOARTHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18
	ACUTE MYELOID LEUKAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BASAL CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LENTIGO MALIGNA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENINGIOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONOCLONAL GAMMOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLARY THYROID CANCER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SQUAMOUS CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	56	3,6	1601	87,9	44	2,7	1,31		Algorithm converged.	0,88	1,96	0,008		Algorithm converged.	-0,004	0,021	1,30		Algorithm converged.	0,88	1,92	0,1822	0,6452	0,77		Algorithm converged.	0,52	1,13
		>= 65	219	12,3	23	10,5	221	12,1	15	6,8	1,61		Algorithm converged.	0,82	3,18	0,037		Algorithm converged.	-0,015	0,090	1,55		Algorithm converged.	0,83	2,89	0,1697		0,65		Algorithm converged.	0,35	1,21
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARPAL TUNNEL SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBRAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	CERVICAL RADICULOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIZZINESS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSGEUSIA	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERCOSTAL NEURALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	LETHARGY	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIGRAINE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	< 65	1564	87,7	7	0,4	1601	87,9	10	0,6	0,72		Algorithm converged.	0,27	1,88	-0,002		Algorithm converged.	-0,007	0,003	0,72		Algorithm converged.	0,27	1,88	0,4977	-	1,40		Algorithm converged.	0,53	3,66
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	< 65	1564	87,7	8	0,5	1601	87,9	2	0,1	4,11		Algorithm converged.	0,87	19,39	0,004		Algorithm converged.	0,000	0,008	4,09		Algorithm converged.	0,87	19,25	0,0743	-	0,24		Algorithm converged.	0,05	1,15
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL MOTOR NEUROPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL SENSORY NEUROPATHY	< 65	1564	87,7	9	0,6	1601	87,9	5	0,3	1,85		Algorithm converged.	0,62	5,52	0,003		Algorithm converged.	-0,002	0,007	1,84		Algorithm converged.	0,62	5,49	0,2722	-	0,54		Algorithm converged.	0,18	1,62
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83
	POLYNEUROPATHY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PRESYNCOPE	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SCIATICA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	< 65	1564	87,7	9	0,6	1601	87,9	12	0,7	0,77		Algorithm converged.	0,32	1,82	-0,002		Algorithm converged.	-0,007	0,004	0,77		Algorithm converged.	0,32	1,82	0,5476	0,0050	1,30		Algorithm converged.	0,55	3,08
		>= 65	219	12,3	10	4,6	221	12,1	1	0,5	10,53		Algorithm converged.	1,34	82,95	0,041		Algorithm converged.	0,012	0,070	10,09		Algorithm converged.	1,30	78,16	0,0269		0,10		Algorithm converged.	0,01	0,77
	THALAMIC INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSIENT ISCHAEMIC ATTACK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PRODUCT ISSUE	-Total	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276 7 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	13	0,8	1601	87,9	9	0,6	1,48		Algorithm converged.	0,63	3,48	0,003		Algorithm converged.	-0,003	0,008	1,48		Algorithm converged.	0,63	3,45	0,3655	-	0,68		Algorithm converged.	0,29	1,58
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
	ANXIETY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMOTIONAL DISTRESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	< 65	1564	87,7	6	0,4	1601	87,9	2	0,1	3,08		Algorithm converged.	0,62	15,28	0,003		Algorithm converged.	-0,001	0,006	3,07		Algorithm converged.	0,62	15,19	0,1690	-	0,33		Algorithm converged.	0,07	1,61
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MAJOR DEPRESSION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	MENTAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOTIC DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
	REACTIVE PSYCHOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDAL IDEATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83
	ACUTE KIDNEY INJURY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL					
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86					
	BLADDER PROLAPSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE					
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
	DYSURIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE					
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEPHROLITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RENAL IMPAIRMENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URETERIC OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	< 65	1564	87,7	32	2,0	1601	87,9	36	2,2	0,91		Algorithm converged.	0,56	1,47	-0,002		Algorithm converged.	-0,012	0,008	0,91		Algorithm converged.	0,57	1,46	0,6945	-	1,10		Algorithm converged.	0,69	1,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	AMENORRHOEA	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAVY MENSTRUAL BLEEDING	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENSTRUATION IRREGULAR	< 65	1564	87,7	19	1,2	1601	87,9	22	1,4	0,88		Algorithm converged.	0,48	1,64	-0,002		Algorithm converged.	-0,009	0,006	0,88		Algorithm converged.	0,48	1,63	0,6921	-	1,13		Algorithm converged.	0,61	2,08
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PREMATURE MENOPAUSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DRYNESS	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL PRURITUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	19	1,2	1601	87,9	13	0,8	1,50		Algorithm converged.	0,74	3,05	0,004		Algorithm converged.	-0,003	0,011	1,50		Algorithm converged.	0,74	3,02	0,2607	0,0852	0,67		Algorithm converged.	0,33	1,35
		>= 65	219	12,3	5	2,3	221	12,1	10	4,5	0,49		Algorithm converged.	0,17	1,47	-0,022		Algorithm converged.	-0,056	0,011	0,50		Algorithm converged.	0,18	1,45	0,2047		1,98		Algorithm converged.	0,69	5,70
	ACUTE RESPIRATORY DISTRESS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHONIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHOSPASM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARRH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	COUGH	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHONIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	EPISTAXIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INTERSTITIAL LUNG DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	LUNG CONSOLIDATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY EMBOLISM	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36
	PULMONARY FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PULMONARY OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RHINORRHOEA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHEEZING	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	59	3,8	1601	87,9	29	1,8	2,13		Algorithm converged.	1,35	3,33	0,020		Algorithm converged.	0,008	0,031	2,08		Algorithm converged.	1,34	3,23	0,0011	0,0458	0,48		Algorithm converged.	0,31	0,74
		>= 65	219	12,3	4	1,8	221	12,1	7	3,2	0,57		Algorithm converged.	0,16	1,97	-0,013		Algorithm converged.	-0,043	0,016	0,58		Algorithm converged.	0,17	1,94	0,3742		1,73		Algorithm converged.	0,51	5,84
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALOPECIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLISTER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS ACNEIFORM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	EXFOLIATIVE RASH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	INGROWING NAIL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISCOLOURATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NAIL TOXICITY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NIGHT SWEATS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOCLASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ONYCHOMADESIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	< 65	1564	87,7	17	1,1	1601	87,9	4	0,2	4,39		Algorithm converged.	1,47	13,07	0,008		Algorithm converged.	0,003	0,014	4,35		Algorithm converged.	1,47	12,90	0,0080	-	0,23		Algorithm converged.	0,08	0,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92						
	PHOTOSENSITIVITY REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	PRURITUS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PSORIASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH MACULAR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULO-PAPULAR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCAR PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN IRRITATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TOXICITY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXIC EPIDERMAL NECROLYSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC SKIN ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URTICARIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST RECONSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	< 65	1564	87,7	28	1,8	1601	87,9	47	2,9	0,60		Algorithm converged.	0,38	0,97	-0,011		Algorithm converged.	-0,022	-0,001	0,61		Algorithm converged.	0,38	0,97	0,0362	0,1512	1,64		Algorithm converged.	1,03	2,60
		>= 65	219	12,3	12	5,5	221	12,1	10	4,5	1,22		Algorithm converged.	0,52	2,89	0,010		Algorithm converged.	-0,031	0,050	1,21		Algorithm converged.	0,53	2,74	0,6466		0,83		Algorithm converged.	0,36	1,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EMBOLISM	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	< 65	1564	87,7	4	0,3	1601	87,9	8	0,5	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,007	0,002	0,51		Algorithm converged.	0,15	1,70	0,2733	-	1,95		Algorithm converged.	0,59	6,48
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSION	< 65	1564	87,7	17	1,1	1601	87,9	26	1,6	0,67		Algorithm converged.	0,36	1,23	-0,005		Algorithm converged.	-0,013	0,003	0,67		Algorithm converged.	0,36	1,23	0,1951	0,6844	1,49		Algorithm converged.	0,81	2,74
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	HYPOTENSION	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	JUGULAR VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ORTHOSTATIC HYPOTENSION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUPERIOR VENA CAVA OCCLUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	4	0,2	0,26		Algorithm converged.	0,03	2,29	-0,002		Algorithm converged.	-0,005	0,001	0,26		Algorithm converged.	0,03	2,29	0,2226	-	3,91		Algorithm converged.	0,44	34,92
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENOUS THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR345_S1.xls
05MAY2022 16:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	96	36,6	252	13,8	78	31,0	1,29		Algorithm converged.	0,89	1,86	0,057		Algorithm converged.	-0,025	0,139	1,18		Algorithm converged.	0,93	1,51	0,1747	0,3026	0,84		Algorithm converged.	0,66	1,08
		Western Europe	814	45,7	243	29,9	824	45,2	248	30,1	0,99		Algorithm converged.	0,80	1,22	-0,002		Algorithm converged.	-0,047	0,042	0,99		Algorithm converged.	0,86	1,15	0,9140		1,01		Algorithm converged.	0,87	1,17
		Asia Pacific	482	27,0	173	35,9	517	28,4	161	31,1	1,24		Algorithm converged.	0,95	1,61	0,048		Algorithm converged.	-0,011	0,106	1,15		Algorithm converged.	0,97	1,37	0,1120		0,87		Algorithm converged.	0,73	1,03
		Latin America	42	2,4	11	26,2	45	2,5	12	26,7	0,98		Algorithm converged.	0,38	2,53	-0,005		Algorithm converged.	-0,190	0,181	0,98		Algorithm converged.	0,49	1,98	0,9599		1,02		Algorithm converged.	0,50	2,05
		Other	183	10,3	57	31,1	184	10,1	40	21,7	1,63		Algorithm converged.	1,02	2,60	0,094		Algorithm converged.	0,004	0,184	1,43		Algorithm converged.	1,01	2,03	0,0432		0,70		Algorithm converged.	0,49	0,99
	AGRANULOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	USA/Canada	262	14,7	41	15,6	252	13,8	26	10,3	1,61		Algorithm converged.	0,95	2,73	0,053		Algorithm converged.	-0,005	0,111	1,52		Algorithm converged.	0,96	2,40	0,0759	-	0,66		Algorithm converged.	0,42	1,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	31	3,8	824	45,2	32	3,9	0,98		Algorithm converged.	0,59	1,62	-0,001		Algorithm converged.	-0,019	0,018	0,98		Algorithm converged.	0,60	1,59	0,9370		1,02		Algorithm converged.	0,63	1,66
		Asia Pacific	482	27,0	39	8,1	517	28,4	22	4,3	1,98		Algorithm converged.	1,16	3,39	0,038		Algorithm converged.	0,008	0,068	1,90		Algorithm converged.	1,14	3,16	0,0131		0,53		Algorithm converged.	0,32	0,87
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31
	BLOOD DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE MARROW FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	21	8,0	252	13,8	23	9,1	0,87		Algorithm converged.	0,47	1,61	-0,011		Algorithm converged.	-0,060	0,037	0,88		Algorithm converged.	0,50	1,55	0,6527	-	1,14		Algorithm converged.	0,65	2,00
		Western Europe	814	45,7	97	11,9	824	45,2	100	12,1	0,98		Algorithm converged.	0,73	1,32	-0,002		Algorithm converged.	-0,034	0,029	0,98		Algorithm converged.	0,76	1,28	0,8914		1,02		Algorithm converged.	0,78	1,32
		Asia Pacific	482	27,0	74	15,4	517	28,4	56	10,8	1,49		Algorithm converged.	1,03	2,17	0,045		Algorithm converged.	0,003	0,087	1,42		Algorithm converged.	1,02	1,96	0,0350		0,71		Algorithm converged.	0,51	0,98
		Latin America	42	2,4	5	11,9	45	2,5	3	6,7	1,89		Algorithm converged.	0,42	8,46	0,052		Algorithm converged.	-0,070	0,174	1,79		Algorithm converged.	0,45	7,01	0,4062		0,56		Algorithm converged.	0,14	2,20
		Other	183	10,3	15	8,2	184	10,1	8	4,3	1,96		Algorithm converged.	0,81	4,75	0,038		Algorithm converged.	-0,011	0,088	1,89		Algorithm converged.	0,82	4,34	0,1359		0,53		Algorithm converged.	0,23	1,22
	GRANULOCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	5	1,0	517	28,4	6	1,2	0,89		Algorithm converged.	0,27	2,94	-0,001		Algorithm converged.	-0,014	0,012		0,89		Algorithm converged.	0,27	2,91	0,8522			1,12		Algorithm converged.	0,34	3,64	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	HAEMATOTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	IRON DEFICIENCY ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	LEUKOPENIA	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033	1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31	
		Western Europe	814	45,7	22	2,7	824	45,2	41	5,0	0,53		Algorithm converged.	0,31	0,90	-0,023		Algorithm converged.	-0,041	-0,004	0,54		Algorithm converged.	0,33	0,90	0,0187		1,84		Algorithm converged.	1,11	3,06	
		Asia Pacific	482	27,0	35	7,3	517	28,4	43	8,3	0,86		Algorithm converged.	0,54	1,37	-0,011		Algorithm converged.	-0,044	0,023	0,87		Algorithm converged.	0,57	1,34	0,5347		1,15		Algorithm converged.	0,75	1,76	
		Latin America	42	2,4	1	2,4	45	2,5	3	6,7	0,34		Algorithm converged.	0,03	3,42	-0,043		Algorithm converged.	-0,129	0,043	0,36		Algorithm converged.	0,04	3,30	0,3642		2,80		Algorithm converged.	0,30	25,88	
		Other	183	10,3	14	7,7	184	10,1	5	2,7	2,97		Algorithm converged.	1,05	8,41	0,049		Algorithm converged.	0,004	0,094	2,82		Algorithm converged.	1,04	7,66	0,0426		0,36		Algorithm converged.	0,13	0,97	
	LYMPHOPENIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	6	1,2	517	28,4	8	1,5	0,80		Algorithm converged.	0,28	2,33	-0,003		Algorithm converged.	-0,018	0,012	0,80		Algorithm converged.	0,28	2,30	0,6850		1,24		Algorithm converged.	0,43	3,56
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	USA/Canada	262	14,7	50	19,1	252	13,8	35	13,9	1,46		Algorithm converged.	0,91	2,34	0,052		Algorithm converged.	-0,012	0,116	1,37		Algorithm converged.	0,92	2,04	0,1156	0,5132	0,73		Algorithm converged.	0,49	1,08
		Western Europe	814	45,7	125	15,4	824	45,2	123	14,9	1,03		Algorithm converged.	0,79	1,35	0,004		Algorithm converged.	-0,030	0,039	1,03		Algorithm converged.	0,82	1,29	0,8086		0,97		Algorithm converged.	0,77	1,22
		Asia Pacific	482	27,0	82	17,0	517	28,4	88	17,0	1,00		Algorithm converged.	0,72	1,39	0,000		Algorithm converged.	-0,047	0,047	1,00		Algorithm converged.	0,76	1,31	0,9970		1,00		Algorithm converged.	0,76	1,32
		Latin America	42	2,4	6	14,3	45	2,5	9	20,0	0,67		Algorithm converged.	0,22	2,07	-0,057		Algorithm converged.	-0,215	0,101	0,71		Algorithm converged.	0,28	1,84	0,4846		1,40		Algorithm converged.	0,54	3,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	37	20,2	184	10,1	29	15,8	1,35		Algorithm converged.	0,79	2,32	0,045		Algorithm converged.	-0,034	0,123		1,28		Algorithm converged.	0,83	1,99	0,2682		0,78		Algorithm converged.	0,50	1,21
	PANCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	USA/Canada	262	14,7	8	3,1	252	13,8	10	4,0	0,76		Algorithm converged.	0,30	1,96	-0,009		Algorithm converged.	-0,041	0,023		0,77		Algorithm converged.	0,31	1,92	0,5739	-	1,30		Algorithm converged.	0,52	3,24
		Western Europe	814	45,7	4	0,5	824	45,2	9	1,1	0,45		Algorithm converged.	0,14	1,46	-0,006		Algorithm converged.	-0,015	0,003		0,45		Algorithm converged.	0,14	1,46	0,1823		2,22		Algorithm converged.	0,69	7,19
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012		1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	4	1,6	1,45		Algorithm converged.	0,41	5,21	0,007		Algorithm converged.	-0,017	0,031		1,44		Algorithm converged.	0,41	5,05	0,5665	-	0,69		Algorithm converged.	0,20	2,43
		Western Europe	814	45,7	16	2,0	824	45,2	11	1,3	1,48		Algorithm converged.	0,68	3,21	0,006		Algorithm converged.	-0,006	0,019		1,47		Algorithm converged.	0,69	3,15	0,3194		0,68		Algorithm converged.	0,32	1,45
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005		0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034	1,34		Algorithm converged.	0,30	5,91	0,6984		0,75		Algorithm converged.	0,17	3,29
	ACUTE CORONARY SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIAL FIBRILLATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ATRIAL THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BRADYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	7	0,9	824	45,2	4	0,5	1,78		Algorithm converged.	0,52	6,10	0,004		Algorithm converged.	-0,004	0,012		1,77		Algorithm converged.	0,52	6,03	0,3601		0,56		Algorithm converged.	0,17	1,92
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE CONGESTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MITRAL VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	PERICARDIAL EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	STRESS CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPRAVENTRICULAR TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA PAROXYSMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRICUSPID VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR FIBRILLATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
	APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE					
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE					
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
	PYLORIC STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	EXTERNAL EAR INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOACUSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	VESTIBULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
ENDOCRINE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	GOITRE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARACT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk											
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL								
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE								
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
	DRY EYE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE								
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE								
	LACRIMATION INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE								

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL VASCULAR DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS FLOATERS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	52	19,8	252	13,8	26	10,3	2,15		Algorithm converged.	1,30	3,57	0,095		Algorithm converged.	0,034	0,156	1,92		Algorithm converged.	1,24	2,98	0,0034	-	0,52		Algorithm converged.	0,34	0,81
		Western Europe	814	45,7	139	17,1	824	45,2	97	11,8	1,54		Algorithm converged.	1,17	2,04	0,053		Algorithm converged.	0,019	0,087	1,45		Algorithm converged.	1,14	1,85	0,0024		0,69		Algorithm converged.	0,54	0,88
		Asia Pacific	482	27,0	59	12,2	517	28,4	39	7,5	1,71		Algorithm converged.	1,12	2,62	0,047		Algorithm converged.	0,010	0,084	1,62		Algorithm converged.	1,10	2,38	0,0137		0,62		Algorithm converged.	0,42	0,91
		Latin America	42	2,4	5	11,9	45	2,5	2	4,4	2,91		Algorithm converged.	0,53	15,87	0,075		Algorithm converged.	-0,040	0,190	2,68		Algorithm converged.	0,55	13,07	0,2231		0,37		Algorithm converged.	0,08	1,82
		Other	183	10,3	13	7,1	184	10,1	5	2,7	2,74		Algorithm converged.	0,96	7,84	0,044		Algorithm converged.	0,000	0,088	2,61		Algorithm converged.	0,95	7,18	0,0624		0,38		Algorithm converged.	0,14	1,05
	ABDOMINAL PAIN	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ABDOMINAL PAIN UPPER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ANAL FISSURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISTULA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS ISCHAEMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009	1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DENTAL CARIES	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	USA/Canada	262	14,7	42	16,0	252	13,8	9	3,6	5,15		Algorithm converged.	2,45	10,83	0,125		Algorithm converged.	0,075	0,175	4,49		Algorithm converged.	2,23	9,03	<.0001	-	0,22		Algorithm converged.	0,11	0,45
		Western Europe	814	45,7	83	10,2	824	45,2	47	5,7	1,88		Algorithm converged.	1,29	2,72	0,045		Algorithm converged.	0,019	0,071	1,79		Algorithm converged.	1,27	2,52	0,0009		0,56		Algorithm converged.	0,40	0,79
		Asia Pacific	482	27,0	34	7,1	517	28,4	13	2,5	2,94		Algorithm converged.	1,53	5,65	0,045		Algorithm converged.	0,019	0,072	2,81		Algorithm converged.	1,50	5,25	0,0013		0,36		Algorithm converged.	0,19	0,67
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	9	4,9	184	10,1	1	0,5	9,47		Algorithm converged.	1,19	75,49	0,044		Algorithm converged.	0,011	0,077	9,05		Algorithm converged.	1,16	70,70	0,0357		0,11		Algorithm converged.	0,01	0,86
	DRY MOUTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ENTERITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ENTEROCOLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	GASTRIC ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLOSSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INTESTINAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INTUSSUSCEPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LOOSE TOOTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MOUTH ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	NAUSEA	USA/Canada	262	14,7	5	1,9	252	13,8	8	3,2	0,59		Algorithm converged.	0,19	1,84	-0,013		Algorithm converged.	-0,040	0,015		0,60		Algorithm converged.	0,20	1,81	0,3662	-		1,66		Algorithm converged.	0,55	5,02
		Western Europe	814	45,7	17	2,1	824	45,2	23	2,8	0,74		Algorithm converged.	0,39	1,40	-0,007		Algorithm converged.	-0,022	0,008		0,75		Algorithm converged.	0,40	1,39	0,3587			1,34		Algorithm converged.	0,72	2,48
		Asia Pacific	482	27,0	12	2,5	517	28,4	10	1,9	1,29		Algorithm converged.	0,55	3,02	0,006		Algorithm converged.	-0,013	0,024		1,29		Algorithm converged.	0,56	2,95	0,5511			0,78		Algorithm converged.	0,34	1,78
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606			0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969			0,99		Algorithm converged.	0,06	15,78
	ORAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	24	2,9	824	45,2	11	1,3	2,25		Algorithm converged.	1,09	4,61	0,016		Algorithm converged.	0,002	0,030	2,21		Algorithm converged.	1,09	4,48	0,0281		0,45		Algorithm converged.	0,22	0,92
		Asia Pacific	482	27,0	9	1,9	517	28,4	6	1,2	1,62		Algorithm converged.	0,57	4,59	0,007		Algorithm converged.	-0,008	0,022	1,61		Algorithm converged.	0,58	4,49	0,3634		0,62		Algorithm converged.	0,22	1,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812879 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VOMITING	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021		0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	15	1,8	824	45,2	14	1,7	1,09		Algorithm converged.	0,52	2,26	0,001		Algorithm converged.	-0,011	0,014		1,08		Algorithm converged.	0,53	2,23	0,8255		0,92		Algorithm converged.	0,45	1,90
		Asia Pacific	482	27,0	10	2,1	517	28,4	10	1,9	1,07		Algorithm converged.	0,44	2,60	0,001		Algorithm converged.	-0,016	0,019		1,07		Algorithm converged.	0,45	2,55	0,8742		0,93		Algorithm converged.	0,39	2,22
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	4	2,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	22	8,4	252	13,8	22	8,7	0,96		Algorithm converged.	0,52	1,78	-0,003		Algorithm converged.	-0,052	0,045		0,96		Algorithm converged.	0,55	1,69	0,8926	-	1,04		Algorithm converged.	0,59	1,83
		Western Europe	814	45,7	80	9,8	824	45,2	79	9,6	1,03		Algorithm converged.	0,74	1,43	0,002		Algorithm converged.	-0,026	0,031		1,03		Algorithm converged.	0,76	1,38	0,8694		0,98		Algorithm converged.	0,73	1,31
		Asia Pacific	482	27,0	11	2,3	517	28,4	17	3,3	0,69		Algorithm converged.	0,32	1,48	-0,010		Algorithm converged.	-0,030	0,010		0,69		Algorithm converged.	0,33	1,47	0,3387		1,44		Algorithm converged.	0,68	3,04
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138		3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88
		Other	183	10,3	10	5,5	184	10,1	4	2,2	2,60		Algorithm converged.	0,80	8,45	0,033		Algorithm converged.	-0,006	0,072		2,51		Algorithm converged.	0,80	7,87	0,1135		0,40		Algorithm converged.	0,13	1,25
	ASTHENIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018		0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	17	2,1	824	45,2	26	3,2	0,65		Algorithm converged.	0,35	1,22	-0,011		Algorithm converged.	-0,026	0,005		0,66		Algorithm converged.	0,36	1,21	0,1802		1,51		Algorithm converged.	0,83	2,76
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004		0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	AXILLARY PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHILLS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE RELATED THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FACIAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	USA/Canada	262	14,7	14	5,3	252	13,8	13	5,2	1,04		Algorithm converged.	0,48	2,25	0,002		Algorithm converged.	-0,037	0,040	1,04		Algorithm converged.	0,50	2,16	0,9252	-	0,97		Algorithm converged.	0,46	2,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	39	4,8	824	45,2	26	3,2	1,54		Algorithm converged.	0,93	2,56	0,016		Algorithm converged.	-0,003	0,035	1,52		Algorithm converged.	0,93	2,47	0,0926		0,66		Algorithm converged.	0,40	1,07
		Asia Pacific	482	27,0	8	1,7	517	28,4	9	1,7	0,95		Algorithm converged.	0,36	2,49	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,37	2,45	0,9212		1,05		Algorithm converged.	0,41	2,70
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	7	3,8	184	10,1	1	0,5	7,28		Algorithm converged.	0,89	59,76	0,033		Algorithm converged.	0,003	0,063	7,04		Algorithm converged.	0,87	56,64	0,0666		0,14		Algorithm converged.	0,02	1,14
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENERALISED OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFLUENZA LIKE ILLNESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION SITE EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MALAISE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MASS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DRYNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	17	2,1	824	45,2	8	1,0	2,18		Algorithm converged.	0,93	5,07	0,011		Algorithm converged.	-0,001	0,023	2,15		Algorithm converged.	0,93	4,96	0,0721		0,46		Algorithm converged.	0,20	1,07
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002085 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	OEDEMA PERIPHERAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PYREXIA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC CYTOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	HEPATIC FUNCTION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326			0,47		Algorithm converged.	0,04	5,12						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	HYPERTRANSAMINASAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005		0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95
		Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010		1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055		0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	5	0,6	0,81		Algorithm converged.	0,22	3,02	-0,001		Algorithm converged.	-0,008	0,006	0,81		Algorithm converged.	0,22	3,01	0,7525		1,23		Algorithm converged.	0,33	4,58
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	19	7,3	252	13,8	28	11,1	0,63		Algorithm converged.	0,34	1,15	-0,039		Algorithm converged.	-0,089	0,011	0,65		Algorithm converged.	0,37	1,14	0,1328	-	1,53		Algorithm converged.	0,88	2,67
		Western Europe	814	45,7	72	8,8	824	45,2	58	7,0	1,28		Algorithm converged.	0,89	1,84	0,018		Algorithm converged.	-0,008	0,044	1,26		Algorithm converged.	0,90	1,75	0,1774		0,80		Algorithm converged.	0,57	1,11
		Asia Pacific	482	27,0	28	5,8	517	28,4	32	6,2	0,93		Algorithm converged.	0,55	1,58	-0,004		Algorithm converged.	-0,033	0,026	0,94		Algorithm converged.	0,57	1,53	0,8004		1,07		Algorithm converged.	0,65	1,74
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	5	2,7	184	10,1	5	2,7	1,01		Algorithm converged.	0,29	3,53	0,000		Algorithm converged.	-0,033	0,033	1,01		Algorithm converged.	0,30	3,41	0,9930		0,99		Algorithm converged.	0,29	3,38
	ABDOMINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS LIMB	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	CATHETER SITE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	USA/Canada	262	14,7	4	1,5	252	13,8	6	2,4	0,64		Algorithm converged.	0,18	2,28	-0,009		Algorithm converged.	-0,033	0,015	0,64		Algorithm converged.	0,18	2,25	0,4871	-	1,56		Algorithm converged.	0,45	5,46
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	6	1,2	517	28,4	3	0,6	2,16		Algorithm converged.	0,54	8,68	0,007		Algorithm converged.	-0,005	0,019	2,15		Algorithm converged.	0,54	8,53	0,2785		0,47		Algorithm converged.	0,12	1,85
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CYSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISSEMINATED TUBERCULOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS INTESTINAL PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENDOCARDITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FURUNCLE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010		2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS VIRAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GROIN ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES OPHTHALMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES VIRUS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOCALISED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	LOWER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MASTITIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	MUCOSAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	NAIL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASOPHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	3	0,4	2,37		Algorithm converged.	0,61	9,21	0,005		Algorithm converged.	-0,003	0,013	2,36		Algorithm converged.	0,61	9,10	0,2118		0,42		Algorithm converged.	0,11	1,63
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL CANDIDIASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARONYCHIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC INFLAMMATORY DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010	0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	4	0,8	517	28,4	6	1,2	0,71		Algorithm converged.	0,20	2,54	-0,003		Algorithm converged.	-0,016	0,009	0,72		Algorithm converged.	0,20	2,52	0,6016		1,40		Algorithm converged.	0,40	4,93
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
	PNEUMONIA ASPIRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	PNEUMONIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMONAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSEUDOMONAS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SALPINGO-OOPHORITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEPSIS	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026		1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002		0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERRATIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	SKIN INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-		2,08		Algorithm converged.	0,19	22,79	
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003		0,51		Algorithm converged.	0,09	2,76	0,4310			1,98		Algorithm converged.	0,36	10,76	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	SOFT TISSUE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	URINARY TRACT INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26	
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	URINARY TRACT INFECTION ENTEROCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROSEPSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION STAPHYLOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	5	2,0	1,16		Algorithm converged.	0,35	3,84	0,003		Algorithm converged.	-0,022	0,028	1,15		Algorithm converged.	0,36	3,73	0,8108	-	0,87		Algorithm converged.	0,27	2,80
		Western Europe	814	45,7	14	1,7	824	45,2	14	1,7	1,01		Algorithm converged.	0,48	2,14	0,000		Algorithm converged.	-0,012	0,013	1,01		Algorithm converged.	0,49	2,11	0,9740		0,99		Algorithm converged.	0,47	2,06
		Asia Pacific	482	27,0	7	1,5	517	28,4	6	1,2	1,26		Algorithm converged.	0,42	3,76	0,003		Algorithm converged.	-0,011	0,017	1,25		Algorithm converged.	0,42	3,70	0,6850		0,80		Algorithm converged.	0,27	2,36
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	4	2,2	0,50		Algorithm converged.	0,09	2,75	-0,011		Algorithm converged.	-0,037	0,015	0,50		Algorithm converged.	0,09	2,71	0,4238		1,99		Algorithm converged.	0,37	10,73
	ACCIDENTAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL					
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE					
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	FALL	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE					
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	FEMORAL NECK FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOOT FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ILIUM FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTENTIONAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIGAMENT SPRAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER LIMB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOCONIOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX TRAUMATIC	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	POST PROCEDURAL HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	POST PROCEDURAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PROCEDURAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION SKIN INJURY	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIUS FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECALL PHENOMENON	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEROMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THERMAL BURN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TIBIA FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ULNA FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	VASCULAR ACCESS COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND DEHISCENCE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	WOUND HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	WRIST FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
INVESTIGATION	-Total	USA/Canada	262	14,7	32	12,2	252	13,8	28	11,1	1,11		Algorithm converged.	0,65	1,91	0,011		Algorithm converged.	-0,044	0,067	1,10		Algorithm converged.	0,68	1,77	0,6973	-	0,91		Algorithm converged.	0,56	1,47	
		Western Europe	814	45,7	99	12,2	824	45,2	124	15,0	0,78		Algorithm converged.	0,59	1,04	-0,029		Algorithm converged.	-0,062	0,004	0,81		Algorithm converged.	0,63	1,03	0,0895		1,24		Algorithm converged.	0,97	1,58	
		Asia Pacific	482	27,0	155	32,2	517	28,4	137	26,5	1,31		Algorithm converged.	1,00	1,73	0,057		Algorithm converged.	0,000	0,113	1,21		Algorithm converged.	1,00	1,47	0,0499		0,82		Algorithm converged.	0,68	1,00	
		Latin America	42	2,4	3	7,1	45	2,5	3	6,7	1,08		Algorithm converged.	0,21	5,66	0,005		Algorithm converged.	-0,102	0,111	1,07		Algorithm converged.	0,23	5,02	0,9302		0,93		Algorithm converged.	0,20	4,37	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	5	2,7	184	10,1	5	2,7	1,01		Algorithm converged.	0,29	3,53	0,000		Algorithm converged.	-0,033	0,033		1,01		Algorithm converged.	0,30	3,41	0,9930		0,99		Algorithm converged.	0,29	3,38
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	6	0,7	824	45,2	6	0,7	1,01		Algorithm converged.	0,33	3,15	0,000		Algorithm converged.	-0,008	0,008		1,01		Algorithm converged.	0,33	3,13	0,9831		0,99		Algorithm converged.	0,32	3,05

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	8	1,7	517	28,4	9	1,7	0,95		Algorithm converged.	0,36	2,49	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,37	2,45	0,9212		1,05		Algorithm converged.	0,41	2,70
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012	1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD ALKALINE PHOSPHATASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD POTASSIUM DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	C-REACTIVE PROTEIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	USA/Canada	262	14,7	8	3,1	252	13,8	4	1,6	1,95		Algorithm converged.	0,58	6,57	0,015		Algorithm converged.	-0,011	0,041		1,92		Algorithm converged.	0,59	6,31	0,2803	-	0,52		Algorithm converged.	0,16	1,70
		Western Europe	814	45,7	13	1,6	824	45,2	20	2,4	0,65		Algorithm converged.	0,32	1,32	-0,008		Algorithm converged.	-0,022	0,005		0,66		Algorithm converged.	0,33	1,31	0,2355		1,52		Algorithm converged.	0,76	3,03
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014		1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GAMMA-GLUTAMYLTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	7	0,8	0,29		Algorithm converged.	0,06	1,39	-0,006		Algorithm converged.	-0,013	0,001	0,29		Algorithm converged.	0,06	1,39	0,1211		3,46		Algorithm converged.	0,72	16,59
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLOMERULAR FILTRATION RATE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOGLOBIN DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC ENZYME INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER FUNCTION TEST INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LYMPHOCYTE COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005		0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	11	4,2	252	13,8	14	5,6	0,75		Algorithm converged.	0,33	1,67	-0,014		Algorithm converged.	-0,051	0,024		0,76		Algorithm converged.	0,35	1,63	0,4762	-	1,32		Algorithm converged.	0,61	2,86
		Western Europe	814	45,7	46	5,7	824	45,2	62	7,5	0,74		Algorithm converged.	0,50	1,09	-0,019		Algorithm converged.	-0,043	0,005		0,75		Algorithm converged.	0,52	1,09	0,1283		1,33		Algorithm converged.	0,92	1,93
		Asia Pacific	482	27,0	121	25,1	517	28,4	107	20,7	1,28		Algorithm converged.	0,96	1,73	0,044		Algorithm converged.	-0,008	0,096		1,21		Algorithm converged.	0,97	1,52	0,0978		0,82		Algorithm converged.	0,66	1,04
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82	
	NEUTROPHIL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PLATELET COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	7	2,7	252	13,8	2	0,8	3,43		Algorithm converged.	0,71	16,68	0,019		Algorithm converged.	-0,004	0,041	3,37		Algorithm converged.	0,71	16,05	0,1277	-	0,30		Algorithm converged.	0,06	1,42
		Western Europe	814	45,7	7	0,9	824	45,2	3	0,4	2,37		Algorithm converged.	0,61	9,21	0,005		Algorithm converged.	-0,003	0,013	2,36		Algorithm converged.	0,61	9,10	0,2118		0,42		Algorithm converged.	0,11	1,63
		Asia Pacific	482	27,0	5	1,0	517	28,4	5	1,0	1,07		Algorithm converged.	0,31	3,73	0,001		Algorithm converged.	-0,012	0,013	1,07		Algorithm converged.	0,31	3,68	0,9113		0,93		Algorithm converged.	0,27	3,20
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSAMINASES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN T INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE OUTPUT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012		3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WEIGHT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	5	1,9	252	13,8	5	2,0	0,96		Algorithm converged.	0,27	3,36	-0,001		Algorithm converged.	-0,025	0,023	0,96		Algorithm converged.	0,28	3,28	0,9505	-	1,04		Algorithm converged.	0,30	3,55
		Western Europe	814	45,7	29	3,6	824	45,2	27	3,3	1,09		Algorithm converged.	0,64	1,86	0,003		Algorithm converged.	-0,015	0,020	1,09		Algorithm converged.	0,65	1,82	0,7502		0,92		Algorithm converged.	0,55	1,54
		Asia Pacific	482	27,0	55	11,4	517	28,4	31	6,0	2,02		Algorithm converged.	1,28	3,20	0,054		Algorithm converged.	0,019	0,089	1,90		Algorithm converged.	1,25	2,90	0,0028		0,53		Algorithm converged.	0,34	0,80
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812828 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	WHITE BLOOD CELL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	37	14,1	252	13,8	15	6,0	2,60		Algorithm converged.	1,39	4,86	0,082		Algorithm converged.	0,030	0,133	2,37		Algorithm converged.	1,34	4,21	0,0032	-	0,42		Algorithm converged.	0,24	0,75
		Western Europe	814	45,7	22	2,7	824	45,2	12	1,5	1,88		Algorithm converged.	0,92	3,82	0,012		Algorithm converged.	-0,001	0,026	1,86		Algorithm converged.	0,92	3,72	0,0819		0,54		Algorithm converged.	0,27	1,08
		Asia Pacific	482	27,0	25	5,2	517	28,4	17	3,3	1,61		Algorithm converged.	0,86	3,02	0,019		Algorithm converged.	-0,006	0,044	1,58		Algorithm converged.	0,86	2,88	0,1388		0,63		Algorithm converged.	0,35	1,16
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	DECREASED APPETITE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	10	2,1	517	28,4	6	1,2	1,80		Algorithm converged.	0,65	5,00	0,009		Algorithm converged.	-0,007	0,025	1,79		Algorithm converged.	0,65	4,88	0,2570		0,56		Algorithm converged.	0,20	1,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEHYDRATION	USA/Canada	262	14,7	11	4,2	252	13,8	2	0,8	5,48		Algorithm converged.	1,20	24,97	0,034		Algorithm converged.	0,007	0,061	5,29		Algorithm converged.	1,18	23,63	0,0291	-	0,19		Algorithm converged.	0,04	0,84
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIABETES MELLITUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETIC METABOLIC DECOMPENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	FAILURE TO THRIVE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	FLUID RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERGLYCAEMIA	USA/Canada	262	14,7	5	1,9	252	13,8	2	0,8	2,43		Algorithm converged.	0,47	12,65	0,011		Algorithm converged.	-0,009	0,031		2,40		Algorithm converged.	0,47	12,28	0,2916	-	0,42		Algorithm converged.	0,08	2,12	
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2	4,32		Algorithm converged.	0,48	38,77	0,006		Algorithm converged.	-0,003	0,015		4,29		Algorithm converged.	0,48	38,25	0,1920		0,23		Algorithm converged.	0,03	2,08	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERKALAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERMAGNESAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRIGLYCERIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	USA/Canada	262	14,7	16	6,1	252	13,8	5	2,0	3,21		Algorithm converged.	1,16	8,91	0,041		Algorithm converged.	0,008	0,075	3,08		Algorithm converged.	1,14	8,28	0,0259	-	0,32		Algorithm converged.	0,12	0,87
		Western Europe	814	45,7	7	0,9	824	45,2	2	0,2	3,57		Algorithm converged.	0,74	17,21	0,006		Algorithm converged.	-0,001	0,013	3,54		Algorithm converged.	0,74	17,00	0,1139		0,28		Algorithm converged.	0,06	1,35
		Asia Pacific	482	27,0	9	1,9	517	28,4	6	1,2	1,62		Algorithm converged.	0,57	4,59	0,007		Algorithm converged.	-0,008	0,022	1,61		Algorithm converged.	0,58	4,49	0,3634		0,62		Algorithm converged.	0,22	1,73
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	11	4,2	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPONATRAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPROTEINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OBESITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	TETANY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TUMOUR LYSIS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	USA/Canada	262	14,7	7	2,7	252	13,8	10	4,0	0,66		Algorithm converged.	0,25	1,77	-0,013		Algorithm converged.	-0,044	0,018	0,67		Algorithm converged.	0,26	1,74	0,4145	-	1,49		Algorithm converged.	0,57	3,84
		Western Europe	814	45,7	22	2,7	824	45,2	37	4,5	0,59		Algorithm converged.	0,35	1,01	-0,018		Algorithm converged.	-0,036	0,000	0,60		Algorithm converged.	0,36	1,01	0,0551		1,66		Algorithm converged.	0,99	2,79
		Asia Pacific	482	27,0	1	0,2	517	28,4	5	1,0	0,21		Algorithm converged.	0,02	1,83	-0,008		Algorithm converged.	-0,017	0,002	0,21		Algorithm converged.	0,03	1,83	0,1593		4,66		Algorithm converged.	0,55	39,76
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTHRALGIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	8	1,0	824	45,2	18	2,2	0,44		Algorithm converged.	0,19	1,03	-0,012		Algorithm converged.	-0,024	0,000	0,45		Algorithm converged.	0,20	1,03	0,0584		2,22		Algorithm converged.	0,97	5,08
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACK PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BONE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	INTERVERTEBRAL DISC PROTRUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULAR WEAKNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009		1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	11	1,4	824	45,2	17	2,1	0,65		Algorithm converged.	0,30	1,40	-0,007		Algorithm converged.	-0,020	0,005	0,66		Algorithm converged.	0,31	1,39	0,2703		1,53		Algorithm converged.	0,72	3,24
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN IN EXTREMITY	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SJOGREN'S SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL OSTEOARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	5	0,6	824	45,2	7	0,8	0,72		Algorithm converged.	0,23	2,28	-0,002		Algorithm converged.	-0,011	0,006	0,72		Algorithm converged.	0,23	2,27	0,5784		1,38		Algorithm converged.	0,44	4,34	
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	ACUTE MYELOID LEUKAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BASAL CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LENTIGO MALIGNA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MONOCLONAL GAMMOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PAPILLARY THYROID CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL CELL LUNG CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	16	6,1	252	13,8	16	6,3	0,96		Algorithm converged.	0,47	1,96	-0,002		Algorithm converged.	-0,044	0,039	0,96		Algorithm converged.	0,49	1,88	0,9095	-	1,04		Algorithm converged.	0,53	2,03
		Western Europe	814	45,7	51	6,3	824	45,2	29	3,5	1,83		Algorithm converged.	1,15	2,92	0,027		Algorithm converged.	0,007	0,048	1,78		Algorithm converged.	1,14	2,78	0,0112		0,56		Algorithm converged.	0,36	0,88
		Asia Pacific	482	27,0	6	1,2	517	28,4	9	1,7	0,71		Algorithm converged.	0,25	2,01	-0,005		Algorithm converged.	-0,020	0,010	0,72		Algorithm converged.	0,26	1,99	0,5216		1,40		Algorithm converged.	0,50	3,90
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103	2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	BURNING SENSATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	CARPAL TUNNEL SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	CEREBRAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL RADICULOPATHY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSGEUSIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEADACHE	USA/Canada	262	14,7	0	0,0	252	13,8	4	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERCOSTAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LETHARGY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MIGRAINE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	NEUROTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIPHERAL MOTOR NEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL SENSORY NEUROPATHY	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYNEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PRESYNCOPE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SCIATICA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	USA/Canada	262	14,7	6	2,3	252	13,8	7	2,8	0,82		Algorithm converged.	0,27	2,48	-0,005		Algorithm converged.	-0,032	0,022	0,82		Algorithm converged.	0,28	2,42	0,7252	-	1,21		Algorithm converged.	0,41	3,56
		Western Europe	814	45,7	9	1,1	824	45,2	2	0,2	4,60		Algorithm converged.	0,99	21,33	0,009		Algorithm converged.	0,001	0,017	4,56		Algorithm converged.	0,99	21,02	0,0520		0,22		Algorithm converged.	0,05	1,01
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812981 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969			0,99		Algorithm converged.	0,06	15,78
	THALAMIC INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE			NE	NE
PRODUCT ISSUE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE EXTRUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021		0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014		1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANXIETY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	EMOTIONAL DISTRESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE			
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE			
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE			
	INSOMNIA	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015		0,96		Algorithm converged.	0,14	6,78	0,9688	-		1,04		Algorithm converged.	0,15	7,32			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MAJOR DEPRESSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010		0,48		Algorithm converged.	0,09	2,60	0,3955	-		2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008		1,27		Algorithm converged.	0,34	4,70	0,7250			0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006		1,07		Algorithm converged.	0,07	17,10	0,9604			0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLADDER PROLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSURIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEPHROLITHIASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL IMPAIRMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036		2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	16	2,0	824	45,2	27	3,3	0,59		Algorithm converged.	0,32	1,11	-0,013		Algorithm converged.	-0,029	0,002		0,60		Algorithm converged.	0,33	1,10	0,1010		1,67		Algorithm converged.	0,91	3,07

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	6	1,2	517	28,4	7	1,4	0,92		Algorithm converged.	0,31	2,75	-0,001		Algorithm converged.	-0,015	0,013		0,92		Algorithm converged.	0,31	2,72	0,8791		1,09		Algorithm converged.	0,37	3,21
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	1	0,5	4,09		Algorithm converged.	0,45	36,94	0,016		Algorithm converged.	-0,007	0,040		4,02		Algorithm converged.	0,45	35,64	0,2112		0,25		Algorithm converged.	0,03	2,20
	AMENORRHOEA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004		0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEAVY MENSTRUAL BLEEDING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	MENSTRUATION IRREGULAR	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028	3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31	
		Western Europe	814	45,7	9	1,1	824	45,2	15	1,8	0,60		Algorithm converged.	0,26	1,39	-0,007		Algorithm converged.	-0,019	0,004	0,61		Algorithm converged.	0,27	1,38	0,2337		1,65		Algorithm converged.	0,72	3,74	
		Asia Pacific	482	27,0	4	0,8	517	28,4	6	1,2	0,71		Algorithm converged.	0,20	2,54	-0,003		Algorithm converged.	-0,016	0,009	0,72		Algorithm converged.	0,20	2,52	0,6016		1,40		Algorithm converged.	0,40	4,93	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PREMATURE MENOPAUSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	VAGINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DRYNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	6	2,4	0,96		Algorithm converged.	0,31	3,02	-0,001		Algorithm converged.	-0,027	0,025		0,96		Algorithm converged.	0,31	2,94	0,9456	-	1,04		Algorithm converged.	0,34	3,18
		Western Europe	814	45,7	16	2,0	824	45,2	14	1,7	1,16		Algorithm converged.	0,56	2,39	0,003		Algorithm converged.	-0,010	0,016		1,16		Algorithm converged.	0,57	2,35	0,6877		0,86		Algorithm converged.	0,42	1,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE RESPIRATORY DISTRESS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ATELECTASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BRONCHOSPASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATARRH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COUGH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	4	0,5	824	45,2	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,004		Algorithm converged.	-0,011	0,004	0,58		Algorithm converged.	0,17	1,97	0,3810		1,73		Algorithm converged.	0,51	5,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPISTAXIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERSTITIAL LUNG DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL EFFUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RHINORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHEEZING	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033	1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	42	5,2	824	45,2	25	3,0	1,74		Algorithm converged.	1,05	2,88	0,021		Algorithm converged.	0,002	0,040	1,70		Algorithm converged.	1,05	2,76	0,0321		0,59		Algorithm converged.	0,36	0,96
		Asia Pacific	482	27,0	11	2,3	517	28,4	3	0,6	4,00		Algorithm converged.	1,11	14,43	0,017		Algorithm converged.	0,002	0,032	3,93		Algorithm converged.	1,10	14,01	0,0347		0,25		Algorithm converged.	0,07	0,91
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055	0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANGIOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	BLISTER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009		4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ACNEIFORM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG ERUPTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXFOLIATIVE RASH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL DISCOLOURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL TOXICITY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHT SWEATS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOCLASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOMADESIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	12	1,5	824	45,2	4	0,5	3,07		Algorithm converged.	0,99	9,55	0,010		Algorithm converged.	0,000	0,019	3,04		Algorithm converged.	0,98	9,38	0,0535		0,33		Algorithm converged.	0,11	1,02
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHOTOSENSITIVITY REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSORIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	7	0,9	824	45,2	4	0,5	1,78		Algorithm converged.	0,52	6,10	0,004		Algorithm converged.	-0,004	0,012	1,77		Algorithm converged.	0,52	6,03	0,3601		0,56		Algorithm converged.	0,17	1,92
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULAR	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH MACULO-PAPULAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCAR PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN IRRITATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SKIN REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SKIN TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SKIN ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC SKIN ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URTICARIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
SURGICAL AND MEDICAL PROCEDURE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST RECONSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	10	3,8	252	13,8	9	3,6	1,07		Algorithm converged.	0,43	2,68	0,002		Algorithm converged.	-0,030	0,035	1,07		Algorithm converged.	0,44	2,59	0,8829	-	0,94		Algorithm converged.	0,39	2,26
		Western Europe	814	45,7	23	2,8	824	45,2	32	3,9	0,72		Algorithm converged.	0,42	1,24	-0,011		Algorithm converged.	-0,028	0,007	0,73		Algorithm converged.	0,43	1,23	0,2369		1,37		Algorithm converged.	0,81	2,33
		Asia Pacific	482	27,0	4	0,8	517	28,4	8	1,5	0,53		Algorithm converged.	0,16	1,78	-0,007		Algorithm converged.	-0,021	0,006	0,54		Algorithm converged.	0,16	1,77	0,3063		1,86		Algorithm converged.	0,57	6,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	3	1,6	184	10,1	6	3,3	0,49		Algorithm converged.	0,12	2,01	-0,016		Algorithm converged.	-0,048	0,015		0,50		Algorithm converged.	0,13	1,98	0,3254		1,99		Algorithm converged.	0,51	7,83
	AXILLARY VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	USA/Canada	262	14,7	4	1,5	252	13,8	5	2,0	0,77		Algorithm converged.	0,20	2,89	-0,005		Algorithm converged.	-0,027	0,018	0,77		Algorithm converged.	0,21	2,83	0,6935	-	1,30		Algorithm converged.	0,35	4,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	13	1,6	824	45,2	16	1,9	0,82		Algorithm converged.	0,39	1,71	-0,003		Algorithm converged.	-0,016	0,009		0,82		Algorithm converged.	0,40	1,70	0,5975		1,22		Algorithm converged.	0,59	2,51
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012		1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.073145902 3 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	6	3,3	0,33		Algorithm converged.	0,07	1,65	-0,022		Algorithm converged.	-0,051	0,008		0,34		Algorithm converged.	0,07	1,64	0,1770		2,98		Algorithm converged.	0,61	14,59
	HYPOTENSION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017		1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	JUGULAR VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORTHOSTATIC HYPOTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCLAVIAN VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPERIOR VENA CAVA OCCLUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOPHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VENOUS THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR345_S1.xls
05MAY2022 16:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	19	37,3	42	2,3	12	28,6	1,48		Algorithm converged.	0,62	3,57	0,087		Algorithm converged.	-0,104	0,277	1,30		Algorithm converged.	0,72	2,37	0,3830	0,6422	0,77		Algorithm converged.	0,42	1,39
		0 positive nodes, tumor > 1 cm	259	14,5	85	32,8	271	14,9	71	26,2	1,38		Algorithm converged.	0,95	2,00	0,066		Algorithm converged.	-0,011	0,144	1,25		Algorithm converged.	0,96	1,63	0,0959		0,80		Algorithm converged.	0,61	1,04
		1-3 positive nodes	891	50,0	293	32,9	905	49,7	283	31,3	1,08		Algorithm converged.	0,88	1,31	0,016		Algorithm converged.	-0,027	0,059	1,05		Algorithm converged.	0,92	1,20	0,4639		0,95		Algorithm converged.	0,83	1,09
		>= 4 positive nodes	582	32,6	183	31,4	604	33,2	173	28,6	1,14		Algorithm converged.	0,89	1,46	0,028		Algorithm converged.	-0,024	0,080	1,10		Algorithm converged.	0,92	1,31	0,2930		0,91		Algorithm converged.	0,77	1,08
	AGRANULOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	3	7,1	1,73		Algorithm converged.	0,41	7,39	0,046		Algorithm converged.	-0,072	0,164		1,65		Algorithm converged.	0,44	6,19	0,4602	-	0,61		Algorithm converged.	0,16	2,28
		0 positive nodes, tumor > 1 cm	259	14,5	18	6,9	271	14,9	16	5,9	1,19		Algorithm converged.	0,59	2,39	0,010		Algorithm converged.	-0,031	0,052		1,18		Algorithm converged.	0,61	2,26	0,6237		0,85		Algorithm converged.	0,44	1,63
		1-3 positive nodes	891	50,0	51	5,7	905	49,7	39	4,3	1,35		Algorithm converged.	0,88	2,07	0,014		Algorithm converged.	-0,006	0,034		1,33		Algorithm converged.	0,88	1,99	0,1711		0,75		Algorithm converged.	0,50	1,13
		>= 4 positive nodes	582	32,6	45	7,7	604	33,2	28	4,6	1,72		Algorithm converged.	1,06	2,80	0,031		Algorithm converged.	0,004	0,058		1,67		Algorithm converged.	1,06	2,64	0,0285		0,60		Algorithm converged.	0,38	0,95
	BLOOD DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	BONE MARROW FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	9	17,6	42	2,3	6	14,3	1,29		Algorithm converged.	0,42	3,96	0,034		Algorithm converged.	-0,115	0,182	1,24		Algorithm converged.	0,48	3,19	0,6625	0,8825	0,81		Algorithm converged.	0,31	2,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	29	11,2	271	14,9	22	8,1	1,43		Algorithm converged.	0,80	2,55	0,031		Algorithm converged.	-0,020	0,081	1,38		Algorithm converged.	0,81	2,34	0,2320		0,73		Algorithm converged.	0,43	1,23
		1-3 positive nodes	891	50,0	109	12,2	905	49,7	100	11,0	1,12		Algorithm converged.	0,84	1,50	0,012		Algorithm converged.	-0,018	0,042	1,11		Algorithm converged.	0,86	1,43	0,4344		0,90		Algorithm converged.	0,70	1,17
		>= 4 positive nodes	582	32,6	65	11,2	604	33,2	62	10,3	1,10		Algorithm converged.	0,76	1,59	0,009		Algorithm converged.	-0,026	0,044	1,09		Algorithm converged.	0,78	1,51	0,6151		0,92		Algorithm converged.	0,66	1,28
	GRANULOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008	4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	HAEMATOTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRON DEFICIENCY ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LEUKOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	1	2,4	3,49		Algorithm converged.	0,37	32,48	0,055		Algorithm converged.	-0,032	0,142	3,29		Algorithm converged.	0,38	28,36	0,2778	-	0,30		Algorithm converged.	0,04	2,61
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	12	4,4	0,60		Algorithm converged.	0,23	1,55	-0,017		Algorithm converged.	-0,049	0,014	0,61		Algorithm converged.	0,24	1,53	0,2910		1,64		Algorithm converged.	0,66	4,10
		1-3 positive nodes	891	50,0	41	4,6	905	49,7	44	4,9	0,94		Algorithm converged.	0,61	1,46	-0,003		Algorithm converged.	-0,022	0,017	0,95		Algorithm converged.	0,62	1,43	0,7951		1,06		Algorithm converged.	0,70	1,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	27	4,6	604	33,2	40	6,6	0,69		Algorithm converged.	0,42	1,13	-0,020		Algorithm converged.	-0,046	0,006		0,70		Algorithm converged.	0,44	1,13	0,1417		1,43		Algorithm converged.	0,89	2,29	
	LYMPHOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30	
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	4	0,4	1,02		Algorithm converged.	0,25	4,07	0,000		Algorithm converged.	-0,006	0,006	1,02		Algorithm converged.	0,25	4,05	0,9824		0,98		Algorithm converged.	0,25	3,92
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	9	17,6	42	2,3	3	7,1	2,79		Algorithm converged.	0,70	11,04	0,105		Algorithm converged.	-0,025	0,235		2,47		Algorithm converged.	0,71	8,55	0,1532	0,2221	0,40		Algorithm converged.	0,12	1,40
		0 positive nodes, tumor > 1 cm	259	14,5	43	16,6	271	14,9	31	11,4	1,54		Algorithm converged.	0,94	2,53	0,052		Algorithm converged.	-0,007	0,111		1,45		Algorithm converged.	0,94	2,23	0,0890		0,69		Algorithm converged.	0,45	1,06
		1-3 positive nodes	891	50,0	161	18,1	905	49,7	161	17,8	1,02		Algorithm converged.	0,80	1,30	0,003		Algorithm converged.	-0,033	0,038		1,02		Algorithm converged.	0,83	1,24	0,8773		0,98		Algorithm converged.	0,81	1,20
		>= 4 positive nodes	582	32,6	87	14,9	604	33,2	89	14,7	1,02		Algorithm converged.	0,74	1,40	0,002		Algorithm converged.	-0,038	0,043		1,01		Algorithm converged.	0,77	1,33	0,9177		0,99		Algorithm converged.	0,75	1,29
	PANCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	5	1,8	0,83		Algorithm converged.	0,22	3,14	-0,003		Algorithm converged.	-0,025	0,019	0,84		Algorithm converged.	0,23	3,08	0,7892		1,19		Algorithm converged.	0,32	4,40
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	8	0,9	1,14		Algorithm converged.	0,44	2,98	0,001		Algorithm converged.	-0,008	0,010	1,14		Algorithm converged.	0,44	2,95	0,7827		0,88		Algorithm converged.	0,34	2,26
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	10	1,7	0,31		Algorithm converged.	0,08	1,12	-0,011		Algorithm converged.	-0,023	0,000	0,31		Algorithm converged.	0,09	1,13	0,0752		3,21		Algorithm converged.	0,89	11,61
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78						
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	14	1,5	0,65		Algorithm converged.	0,28	1,51	-0,005		Algorithm converged.	-0,016	0,005	0,65		Algorithm converged.	0,28	1,50	0,3155		1,53		Algorithm converged.	0,67	3,52						
		>= 4 positive nodes	582	32,6	15	2,6	604	33,2	6	1,0	2,64		Algorithm converged.	1,02	6,84	0,016		Algorithm converged.	0,001	0,031	2,59		Algorithm converged.	1,01	6,64	0,0468		0,39		Algorithm converged.	0,15	0,99						
	ACUTE CORONARY SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	ATRIAL FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68						
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801536 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE					
	ATRIAL THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRADYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	5	0,6	1,02		Algorithm converged.	0,29	3,52	0,000		Algorithm converged.	-0,007	0,007	1,02		Algorithm converged.	0,30	3,50	0,9803		0,98		Algorithm converged.	0,29	3,39
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	1	0,2	7,34		Algorithm converged.	0,90	59,85	0,010		Algorithm converged.	0,001	0,020	7,26		Algorithm converged.	0,90	58,86	0,0632		0,14		Algorithm converged.	0,02	1,12
	CARDIAC FAILURE CONGESTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959			1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERICARDIAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	STRESS CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUPRAVENTRICULAR TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	TACHYCARDIA PAROXYSMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TRICUSPID VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	VENTRICULAR FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTERNAL EAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOACUSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	VERTIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GOITRE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATARACT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRY EYE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RETINAL VASCULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VITREOUS FLOATERS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	10	19,6	42	2,3	7	16,7	1,22		Algorithm converged.	0,42	3,54	0,029		Algorithm converged.	-0,127	0,186	1,18		Algorithm converged.	0,49	2,82	0,7159	0,7666	0,85		Algorithm converged.	0,35	2,04
		0 positive nodes, tumor > 1 cm	259	14,5	42	16,2	271	14,9	25	9,2	1,90		Algorithm converged.	1,12	3,23	0,070		Algorithm converged.	0,013	0,126	1,76		Algorithm converged.	1,10	2,80	0,0174		0,57		Algorithm converged.	0,36	0,91
		1-3 positive nodes	891	50,0	140	15,7	905	49,7	93	10,3	1,63		Algorithm converged.	1,23	2,15	0,054		Algorithm converged.	0,023	0,085	1,53		Algorithm converged.	1,20	1,95	0,0007		0,65		Algorithm converged.	0,51	0,84
		>= 4 positive nodes	582	32,6	76	13,1	604	33,2	44	7,3	1,91		Algorithm converged.	1,29	2,82	0,058		Algorithm converged.	0,023	0,092	1,79		Algorithm converged.	1,26	2,55	0,0012		0,56		Algorithm converged.	0,39	0,79
	ABDOMINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	5	0,6	1,22		Algorithm converged.	0,37	4,01	0,001		Algorithm converged.	-0,006	0,008	1,22		Algorithm converged.	0,37	3,98	0,7430		0,82		Algorithm converged.	0,25	2,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	ABDOMINAL PAIN UPPER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	ANAL FISSURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ANAL FISTULA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	COLITIS ISCHAEMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
	DENTAL CARIES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082	0,66		Algorithm converged.	0,19	2,30	0,5128	-	1,52		Algorithm converged.	0,43	5,30
		0 positive nodes, tumor > 1 cm	259	14,5	25	9,7	271	14,9	15	5,5	1,82		Algorithm converged.	0,94	3,54	0,041		Algorithm converged.	-0,004	0,086	1,74		Algorithm converged.	0,94	3,23	0,0773		0,57		Algorithm converged.	0,31	1,06
		1-3 positive nodes	891	50,0	90	10,1	905	49,7	35	3,9	2,79		Algorithm converged.	1,87	4,18	0,062		Algorithm converged.	0,039	0,086	2,61		Algorithm converged.	1,79	3,82	<.0001		0,38		Algorithm converged.	0,26	0,56
		>= 4 positive nodes	582	32,6	49	8,4	604	33,2	16	2,6	3,38		Algorithm converged.	1,90	6,01	0,058		Algorithm converged.	0,032	0,084	3,18		Algorithm converged.	1,83	5,52	<.0001		0,31		Algorithm converged.	0,18	0,55
	DRY MOUTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DUODENAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DUODENAL ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO											PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GASTROINTESTINAL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLOSSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHOIDS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOOSE TOOTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MOUTH ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAUSEA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	6	2,2	0,69		Algorithm converged.	0,19	2,48	-0,007		Algorithm converged.	-0,030	0,016		0,70		Algorithm converged.	0,20	2,44	0,5734		1,43		Algorithm converged.	0,41	5,02
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	27	3,0	0,75		Algorithm converged.	0,42	1,34	-0,007		Algorithm converged.	-0,022	0,007		0,75		Algorithm converged.	0,43	1,33	0,3286		1,33		Algorithm converged.	0,75	2,35
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	9	1,5	1,16		Algorithm converged.	0,47	2,87	0,002		Algorithm converged.	-0,012	0,017		1,15		Algorithm converged.	0,47	2,82	0,7546		0,87		Algorithm converged.	0,35	2,12
	ORAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PANCREATITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	4	1,5	1,31		Algorithm converged.	0,35	4,95	0,005		Algorithm converged.	-0,018	0,027	1,31		Algorithm converged.	0,36	4,82	0,6865	-	0,76		Algorithm converged.	0,21	2,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	9	1,0	2,29		Algorithm converged.	1,04	5,05	0,013		Algorithm converged.	0,001	0,024	2,26		Algorithm converged.	1,03	4,93	0,0411		0,44		Algorithm converged.	0,20	0,97
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	5	0,8	2,52		Algorithm converged.	0,88	7,20	0,012		Algorithm converged.	-0,001	0,026	2,49		Algorithm converged.	0,88	7,03	0,0846		0,40		Algorithm converged.	0,14	1,13
	SUBILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VOMITING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	6	2,2	0,34		Algorithm converged.	0,07	1,72	-0,014		Algorithm converged.	-0,035	0,006	0,35		Algorithm converged.	0,07	1,71	0,1945		2,87		Algorithm converged.	0,58	14,08
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	15	1,7	1,08		Algorithm converged.	0,53	2,21	0,001		Algorithm converged.	-0,011	0,013	1,08		Algorithm converged.	0,54	2,18	0,8221		0,92		Algorithm converged.	0,46	1,86
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	11	1,8	1,13		Algorithm converged.	0,50	2,59	0,002		Algorithm converged.	-0,013	0,018	1,13		Algorithm converged.	0,50	2,55	0,7640		0,88		Algorithm converged.	0,39	1,99
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	2	4,8	2,67		Algorithm converged.	0,51	13,97	0,070		Algorithm converged.	-0,039	0,179	2,47		Algorithm converged.	0,53	11,61	0,2519	-	0,40		Algorithm converged.	0,09	1,90
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	15	5,5	1,05		Algorithm converged.	0,50	2,19	0,003		Algorithm converged.	-0,037	0,042	1,05		Algorithm converged.	0,52	2,10	0,8984		0,96		Algorithm converged.	0,48	1,92
		1-3 positive nodes	891	50,0	66	7,4	905	49,7	66	7,3	1,02		Algorithm converged.	0,71	1,45	0,001		Algorithm converged.	-0,023	0,025	1,02		Algorithm converged.	0,73	1,41	0,9259		0,98		Algorithm converged.	0,71	1,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	39	6,7	604	33,2	40	6,6	1,01		Algorithm converged.	0,64	1,60	0,001		Algorithm converged.	-0,028	0,029	1,01		Algorithm converged.	0,66	1,55	0,9568		0,99		Algorithm converged.	0,65	1,51
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	18	2,0	0,90		Algorithm converged.	0,46	1,78	-0,002		Algorithm converged.	-0,015	0,011	0,90		Algorithm converged.	0,46	1,76	0,7640		1,11		Algorithm converged.	0,57	2,16
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	12	2,0	0,51		Algorithm converged.	0,19	1,38	-0,010		Algorithm converged.	-0,023	0,004	0,52		Algorithm converged.	0,20	1,37	0,1865		1,93		Algorithm converged.	0,73	5,10

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CHILLS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FACE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FACIAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	1	2,4	3,49		Algorithm converged.	0,37	32,48	0,055		Algorithm converged.	-0,032	0,142		3,29		Algorithm converged.	0,38	28,36	0,2778	-	0,30		Algorithm converged.	0,04	2,61
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	7	2,6	1,51		Algorithm converged.	0,57	4,04	0,013		Algorithm converged.	-0,017	0,043		1,49		Algorithm converged.	0,58	3,87	0,4073		0,67		Algorithm converged.	0,26	1,73
		1-3 positive nodes	891	50,0	36	4,0	905	49,7	26	2,9	1,42		Algorithm converged.	0,85	2,38	0,012		Algorithm converged.	-0,005	0,029		1,41		Algorithm converged.	0,86	2,31	0,1777		0,71		Algorithm converged.	0,43	1,17
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	15	2,5	1,33		Algorithm converged.	0,67	2,63	0,008		Algorithm converged.	-0,011	0,027		1,31		Algorithm converged.	0,67	2,56	0,4218		0,76		Algorithm converged.	0,39	1,48
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	GENERALISED OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFLUENZA LIKE ILLNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INFUSION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
	MUCOSAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	7	0,8	1,60		Algorithm converged.	0,62	4,16	0,005		Algorithm converged.	-0,005	0,014	1,60		Algorithm converged.	0,62	4,10	0,3312		0,63		Algorithm converged.	0,24	1,61
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	4	0,7	2,09		Algorithm converged.	0,63	6,98	0,007		Algorithm converged.	-0,004	0,019	2,08		Algorithm converged.	0,63	6,86	0,2310		0,48		Algorithm converged.	0,15	1,59
	OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	PYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	8	0,9	0,38		Algorithm converged.	0,10	1,43	-0,005		Algorithm converged.	-0,013	0,002	0,38		Algorithm converged.	0,10	1,43	0,1529		2,63		Algorithm converged.	0,70	9,86
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	CHOLANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FUNCTION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HYPERTRANSAMINASAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95	
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	11	1,2	0,55		Algorithm converged.	0,20	1,50	-0,005		Algorithm converged.	-0,014	0,004	0,55		Algorithm converged.	0,21	1,49	0,2425		1,80		Algorithm converged.	0,67	4,86	
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013	1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003	0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	5	11,9	0,30		Algorithm converged.	0,06	1,64	-0,080		Algorithm converged.	-0,191	0,032	0,33		Algorithm converged.	0,07	1,61	0,1706	-	3,04		Algorithm converged.	0,62	14,86
		0 positive nodes, tumor > 1 cm	259	14,5	11	4,2	271	14,9	19	7,0	0,59		Algorithm converged.	0,27	1,26	-0,028		Algorithm converged.	-0,067	0,011	0,61		Algorithm converged.	0,29	1,25	0,1741		1,65		Algorithm converged.	0,80	3,40
		1-3 positive nodes	891	50,0	71	8,0	905	49,7	51	5,6	1,45		Algorithm converged.	1,00	2,10	0,023		Algorithm converged.	0,000	0,047	1,41		Algorithm converged.	1,00	2,00	0,0508		0,71		Algorithm converged.	0,50	1,00
		>= 4 positive nodes	582	32,6	41	7,0	604	33,2	49	8,1	0,86		Algorithm converged.	0,56	1,32	-0,011		Algorithm converged.	-0,041	0,019	0,87		Algorithm converged.	0,58	1,29	0,4880		1,15		Algorithm converged.	0,77	1,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
	ABSCESS LIMB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE HEPATITIS B	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	BRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	CATHETER SITE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	6	1,0	1,04		Algorithm converged.	0,33	3,24	0,000		Algorithm converged.	-0,011	0,012	1,04		Algorithm converged.	0,34	3,20	0,9485		0,96		Algorithm converged.	0,31	2,97
	CLOSTRIDIUM COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	CLOSTRIDIUM DIFFICILE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CYSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE RELATED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996293 9 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
	DIARRHOEA INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DISSEMINATED TUBERCULOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DIVERTICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	DIVERTICULITIS INTESTINAL PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ENDOCARDITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ESCHERICHIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EYE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	FURUNCLE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	GASTROENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	GASTROENTERITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GROIN ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES OPHTHALMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES VIRUS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOCALISED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006		1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LYMPHANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	MASTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	MUCOSAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008		4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	ORAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	OROPHARYNGITIS FUNGAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PELVIC INFLAMMATORY DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERITONSILLAR ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHLEBITIS INFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	8	0,9	0,63		Algorithm converged.	0,21	1,94	-0,003		Algorithm converged.	-0,011	0,005	0,63		Algorithm converged.	0,21	1,93	0,4238		1,58		Algorithm converged.	0,52	4,80
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	PNEUMONIA ASPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PSEUDOMONAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RECTAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SALPINGO-OOPHORITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004		0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821886 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809			2,46		Algorithm converged.	0,48	12,65			
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	STAPHYLOCOCCAL SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCUTANEOUS ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOOTH ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOOTH INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	URINARY TRACT INFECTION ENTEROCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.87480164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR DEVICE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	WOUND INFECTION STAPHYLOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	3	1,1	1,05		Algorithm converged.	0,21	5,23	0,001		Algorithm converged.	-0,018	0,019	1,05		Algorithm converged.	0,21	5,14	0,9555		0,96		Algorithm converged.	0,19	4,69
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	13	1,4	1,58		Algorithm converged.	0,78	3,19	0,008		Algorithm converged.	-0,004	0,021	1,56		Algorithm converged.	0,78	3,12	0,2062		0,64		Algorithm converged.	0,32	1,28
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	14	2,3	0,51		Algorithm converged.	0,21	1,28	-0,011		Algorithm converged.	-0,026	0,004	0,52		Algorithm converged.	0,21	1,28	0,1531		1,93		Algorithm converged.	0,78	4,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACCIDENTAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	FALL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEMORAL NECK FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FOOT FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRAFT THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	ILIUM FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INCISION SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTENTIONAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIGAMENT SPRAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER LIMB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIATION SKIN INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ROAD TRAFFIC ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THERMAL BURN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TIBIA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ULNA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	11	21,6	42	2,3	6	14,3	1,65		Algorithm converged.	0,55	4,92	0,073		Algorithm converged.	-0,082	0,228	1,51		Algorithm converged.	0,61	3,74	0,3733	0,4321	0,66		Algorithm converged.	0,27	1,64
		0 positive nodes, tumor > 1 cm	259	14,5	48	18,5	271	14,9	40	14,8	1,31		Algorithm converged.	0,83	2,08	0,038		Algorithm converged.	-0,026	0,101	1,26		Algorithm converged.	0,86	1,84	0,2447		0,80		Algorithm converged.	0,54	1,17
		1-3 positive nodes	891	50,0	139	15,6	905	49,7	153	16,9	0,91		Algorithm converged.	0,71	1,17	-0,013		Algorithm converged.	-0,047	0,021	0,92		Algorithm converged.	0,75	1,14	0,4536		1,08		Algorithm converged.	0,88	1,34
		>= 4 positive nodes	582	32,6	96	16,5	604	33,2	98	16,2	1,02		Algorithm converged.	0,75	1,39	0,003		Algorithm converged.	-0,039	0,045	1,02		Algorithm converged.	0,79	1,32	0,9001		0,98		Algorithm converged.	0,76	1,27
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ALANINE AMINOTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	10	1,1	0,71		Algorithm converged.	0,27	1,87	-0,003		Algorithm converged.	-0,012	0,006		0,71		Algorithm converged.	0,27	1,86	0,4869		1,41		Algorithm converged.	0,54	3,68
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	6	1,0	1,21		Algorithm converged.	0,41	3,63	0,002		Algorithm converged.	-0,010	0,014		1,21		Algorithm converged.	0,41	3,58	0,7296		0,83		Algorithm converged.	0,28	2,44
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29	
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69	
	BLOOD ALKALINE PHOSPHATASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD POTASSIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	BLOOD PRESSURE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BLOOD TRIGLYCERIDES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	C-REACTIVE PROTEIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	EJECTION FRACTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	2	0,7	2,11		Algorithm converged.	0,38	11,62	0,008		Algorithm converged.	-0,010	0,026	2,09		Algorithm converged.	0,39	11,33	0,3914		0,48		Algorithm converged.	0,09	2,59	
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	14	1,5	1,02		Algorithm converged.	0,48	2,14	0,000		Algorithm converged.	-0,011	0,012	1,02		Algorithm converged.	0,49	2,12	0,9668		0,98		Algorithm converged.	0,47	2,05	
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	14	2,3	0,74		Algorithm converged.	0,32	1,67	-0,006		Algorithm converged.	-0,022	0,010	0,74		Algorithm converged.	0,33	1,66	0,4652		1,35		Algorithm converged.	0,60	3,01	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL	
	GAMMA-GLUTAMYLTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	5	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9998		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	GLOMERULAR FILTRATION RATE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	HEPATIC ENZYME INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER FUNCTION TEST INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOCYTE COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	7	13,7	42	2,3	5	11,9	1,18		Algorithm converged.	0,34	4,02	0,018		Algorithm converged.	-0,118	0,154	1,15		Algorithm converged.	0,39	3,37	0,7948	0,7181	0,87		Algorithm converged.	0,30	2,54
		0 positive nodes, tumor > 1 cm	259	14,5	33	12,7	271	14,9	30	11,1	1,17		Algorithm converged.	0,69	1,99	0,017		Algorithm converged.	-0,038	0,072	1,15		Algorithm converged.	0,72	1,83	0,5527		0,87		Algorithm converged.	0,55	1,38
		1-3 positive nodes	891	50,0	81	9,1	905	49,7	94	10,4	0,86		Algorithm converged.	0,63	1,18	-0,013		Algorithm converged.	-0,040	0,014	0,88		Algorithm converged.	0,66	1,16	0,3550		1,14		Algorithm converged.	0,86	1,52
		>= 4 positive nodes	582	32,6	59	10,1	604	33,2	58	9,6	1,06		Algorithm converged.	0,72	1,56	0,005		Algorithm converged.	-0,029	0,039	1,06		Algorithm converged.	0,75	1,49	0,7575		0,95		Algorithm converged.	0,67	1,34
	NEUTROPHIL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLATELET COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013	0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	2	0,2	6,69		Algorithm converged.	1,50	29,71	0,012		Algorithm converged.	0,004	0,021	6,60		Algorithm converged.	1,49	29,17	0,0128		0,15		Algorithm converged.	0,03	0,67
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	TRANSAMINASES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN T INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINE OUTPUT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	WEIGHT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	1	2,4	4,46		Algorithm converged.	0,50	39,74	0,074		Algorithm converged.	-0,020	0,168		4,12		Algorithm converged.	0,50	33,89	0,1882	-	0,24		Algorithm converged.	0,03	2,00
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	9	3,3	1,54		Algorithm converged.	0,65	3,66	0,017		Algorithm converged.	-0,017	0,051		1,51		Algorithm converged.	0,66	3,48	0,3310		0,66		Algorithm converged.	0,29	1,52
		1-3 positive nodes	891	50,0	39	4,4	905	49,7	36	4,0	1,10		Algorithm converged.	0,70	1,76	0,004		Algorithm converged.	-0,015	0,023		1,10		Algorithm converged.	0,71	1,71	0,6725		0,91		Algorithm converged.	0,58	1,42
		>= 4 positive nodes	582	32,6	35	6,0	604	33,2	19	3,1	1,97		Algorithm converged.	1,11	3,49	0,029		Algorithm converged.	0,005	0,052		1,91		Algorithm converged.	1,11	3,30	0,0202		0,52		Algorithm converged.	0,30	0,90
	WHITE BLOOD CELL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048		0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	11	4,2	271	14,9	9	3,3	1,29		Algorithm converged.	0,53	3,17	0,009		Algorithm converged.	-0,023	0,042		1,28		Algorithm converged.	0,54	3,04	0,5770		0,78		Algorithm converged.	0,33	1,86
		1-3 positive nodes	891	50,0	46	5,2	905	49,7	23	2,5	2,09		Algorithm converged.	1,25	3,47	0,026		Algorithm converged.	0,008	0,044		2,03		Algorithm converged.	1,24	3,32	0,0047		0,49		Algorithm converged.	0,30	0,81
		>= 4 positive nodes	582	32,6	30	5,2	604	33,2	11	1,8	2,93		Algorithm converged.	1,45	5,90	0,033		Algorithm converged.	0,012	0,054		2,83		Algorithm converged.	1,43	5,59	0,0028		0,35		Algorithm converged.	0,18	0,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	1	0,1	11,30		Algorithm converged.	1,46	87,71	0,011		Algorithm converged.	0,004	0,019		11,17		Algorithm converged.	1,45	86,36	0,0207		0,09		Algorithm converged.	0,01	0,69	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	DIABETES MELLITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIABETIC METABOLIC DECOMPENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAILURE TO THRIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPERGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959			1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875			0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013		1,73		Algorithm converged.	0,42	7,20	0,4517			0,58		Algorithm converged.	0,14	2,41
	HYPERKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTRIGLYCERIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023		3,14		Algorithm converged.	0,33	29,98	0,3205			0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	9	1,0	2,29		Algorithm converged.	1,04	5,05	0,013		Algorithm converged.	0,001	0,024		2,26		Algorithm converged.	1,03	4,93	0,0411			0,44		Algorithm converged.	0,20	0,97
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	4	0,7	2,62		Algorithm converged.	0,82	8,41	0,011		Algorithm converged.	-0,002	0,023		2,59		Algorithm converged.	0,82	8,23	0,1054			0,39		Algorithm converged.	0,12	1,22
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	1	0,1	8,19		Algorithm converged.	1,02	65,62	0,008		Algorithm converged.	0,001	0,014		8,13		Algorithm converged.	1,02	64,83	0,0480			0,12		Algorithm converged.	0,02	0,98
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPONATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOPROTEINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPOVOLAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LIPOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OBESITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TETANY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TUMOUR LYSIS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	10	3,7	0,41		Algorithm converged.	0,13	1,32	-0,021		Algorithm converged.	-0,048	0,006	0,42		Algorithm converged.	0,13	1,32	0,1366		2,39		Algorithm converged.	0,76	7,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	29	3,2	0,69		Algorithm converged.	0,39	1,24	-0,010		Algorithm converged.	-0,025	0,005	0,70		Algorithm converged.	0,40	1,23	0,2145		1,43		Algorithm converged.	0,81	2,50						
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	15	2,5	0,62		Algorithm converged.	0,27	1,42	-0,009		Algorithm converged.	-0,025	0,007	0,62		Algorithm converged.	0,27	1,41	0,2566		1,61		Algorithm converged.	0,71	3,64						
	ARTHRALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016	0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64						
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	13	1,4	0,47		Algorithm converged.	0,18	1,23	-0,008		Algorithm converged.	-0,017	0,002	0,47		Algorithm converged.	0,18	1,23	0,1231		2,13		Algorithm converged.	0,81	5,59						
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46						
	BACK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	BONE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,004		Algorithm converged.	-0,010	0,001		0,20		Algorithm converged.	0,02	1,74	0,1453		4,92		Algorithm converged.	0,58	42,05
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERVERTEBRAL DISC PROTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULAR WEAKNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	MYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	11	1,2	0,64		Algorithm converged.	0,25	1,67	-0,004		Algorithm converged.	-0,013	0,005	0,65		Algorithm converged.	0,25	1,66	0,3645		1,55		Algorithm converged.	0,60	3,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	6	1,0	0,69		Algorithm converged.	0,19	2,46	-0,003		Algorithm converged.	-0,013	0,007		0,69		Algorithm converged.	0,20	2,44	0,5667		1,45		Algorithm converged.	0,41	5,10
	PAIN IN EXTREMITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SJOGREN'S SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SPINAL OSTEOARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SPINAL STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,004		Algorithm converged.	-0,011	0,002	0,34		Algorithm converged.	0,07	1,67	0,1840		2,95		Algorithm converged.	0,60	14,59
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	2	0,3	2,08		Algorithm converged.	0,38	11,42	0,004		Algorithm converged.	-0,005	0,012	2,08		Algorithm converged.	0,38	11,29	0,3980		0,48		Algorithm converged.	0,09	2,62
	ACUTE MYELOID LEUKAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ADENOCARCINOMA PANCREAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST CANCER IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LENTIGO MALIGNA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
	MENINGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
	MONOCLONAL GAMMOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PAPILLARY THYROID CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE LEIOMYOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082	0,66		Algorithm converged.	0,19	2,30	0,5128	-	1,52		Algorithm converged.	0,43	5,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	9	3,3	1,17		Algorithm converged.	0,47	2,93	0,005		Algorithm converged.	-0,026	0,037	1,16		Algorithm converged.	0,48	2,81	0,7385		0,86		Algorithm converged.	0,36	2,08
		1-3 positive nodes	891	50,0	40	4,5	905	49,7	28	3,1	1,47		Algorithm converged.	0,90	2,41	0,014		Algorithm converged.	-0,004	0,032	1,45		Algorithm converged.	0,90	2,33	0,1237		0,69		Algorithm converged.	0,43	1,11
		>= 4 positive nodes	582	32,6	25	4,3	604	33,2	17	2,8	1,55		Algorithm converged.	0,83	2,90	0,015		Algorithm converged.	-0,006	0,036	1,53		Algorithm converged.	0,83	2,80	0,1712		0,66		Algorithm converged.	0,36	1,20
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARPAL TUNNEL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CERVICAL RADICULOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIZZINESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	HAEMORRHAGE INTRACRANIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71	
	INTERCOSTAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LETHARGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 34.259950313 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MIGRAINE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROPATHY PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	7	0,8	0,14		Algorithm converged.	0,02	1,17	-0,007		Algorithm converged.	-0,013	0,000	0,15		Algorithm converged.	0,02	1,18	0,0707		6,89		Algorithm converged.	0,85	55,90
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	NEUROTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 22.861526165 is greater than the limit of 0.0001. The convergence is questionable.	-0,041	0,096	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PERIPHERAL MOTOR NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL SENSORY NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	POLYNEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PRESYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCIATICA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73						
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	6	0,7	1,36		Algorithm converged.	0,47	3,93	0,002		Algorithm converged.	-0,006	0,010	1,35		Algorithm converged.	0,47	3,89	0,5730		0,74		Algorithm converged.	0,26	2,12						
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	4	0,7	1,83		Algorithm converged.	0,53	6,27	0,005		Algorithm converged.	-0,006	0,016	1,82		Algorithm converged.	0,53	6,17	0,3390		0,55		Algorithm converged.	0,16	1,87						
	THALAMIC INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSIENT ISCHAEMIC ATTACK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
PRODUCT ISSUE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	DEVICE EXTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE			
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-		1,21		Algorithm converged.	0,08	18,83			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	5	0,6	2,04		Algorithm converged.	0,70	6,00	0,006		Algorithm converged.	-0,003	0,014	2,03		Algorithm converged.	0,70	5,92	0,1940		0,49		Algorithm converged.	0,17	1,43
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE				
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE				
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005		1,02		Algorithm converged.	0,21	5,02	0,9847			0,98		Algorithm converged.	0,20	4,86				
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20				
	EMOTIONAL DISTRESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE				
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE				
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE				

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MAJOR DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDE ATTEMPT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82	
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	5	0,8	1,25		Algorithm converged.	0,38	4,11	0,002		Algorithm converged.	-0,009	0,013		1,25		Algorithm converged.	0,38	4,06	0,7158		0,80		Algorithm converged.	0,25	2,62	
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013		4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	BLADDER PROLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE		
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE		
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		
	DYSURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE		
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEPHROLITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETERIC OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY TRACT OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029	1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	21	2,3	0,82		Algorithm converged.	0,43	1,56	-0,004		Algorithm converged.	-0,017	0,009	0,82		Algorithm converged.	0,44	1,55	0,5443		1,22		Algorithm converged.	0,65	2,29
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	13	2,2	0,71		Algorithm converged.	0,30	1,68	-0,006		Algorithm converged.	-0,021	0,009	0,72		Algorithm converged.	0,31	1,67	0,4417		1,39		Algorithm converged.	0,60	3,23

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMENORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	4	0,4	1,27		Algorithm converged.	0,34	4,75	0,001		Algorithm converged.	-0,005	0,008	1,27		Algorithm converged.	0,34	4,71	0,7213		0,79		Algorithm converged.	0,21	2,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	BREAST HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HEAVY MENSTRUAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUATION IRREGULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032		2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	14	1,5	0,80		Algorithm converged.	0,36	1,76	-0,003		Algorithm converged.	-0,014	0,008		0,80		Algorithm converged.	0,36	1,75	0,5729		1,25		Algorithm converged.	0,57	2,75
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005		0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	PREMATURE MENOPAUSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	3	1,1	2,85		Algorithm converged.	0,75	10,85	0,020		Algorithm converged.	-0,005	0,044	2,79		Algorithm converged.	0,75	10,40	0,1264		0,36		Algorithm converged.	0,10	1,34
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	10	1,1	1,12		Algorithm converged.	0,47	2,65	0,001		Algorithm converged.	-0,009	0,011	1,12		Algorithm converged.	0,48	2,62	0,7985		0,90		Algorithm converged.	0,38	2,10
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	9	1,5	0,34		Algorithm converged.	0,09	1,27	-0,010		Algorithm converged.	-0,021	0,002	0,35		Algorithm converged.	0,09	1,27	0,1100		2,89		Algorithm converged.	0,79	10,62
	ACUTE RESPIRATORY DISTRESS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASTHMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BRONCHOSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARRH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DYSPHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002		0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPISTAXIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	INTERSTITIAL LUNG DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG CONSOLIDATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PLEURAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PNEUMOTHORAX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHINORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	WHEEZING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83	
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	5	1,8	2,81		Algorithm converged.	0,99	8,00	0,032		Algorithm converged.	0,001	0,063		2,72		Algorithm converged.	0,98	7,52	0,0538		0,37		Algorithm converged.	0,13	1,02	
		1-3 positive nodes	891	50,0	35	3,9	905	49,7	18	2,0	2,01		Algorithm converged.	1,13	3,58	0,019		Algorithm converged.	0,004	0,035		1,97		Algorithm converged.	1,13	3,46	0,0174		0,51		Algorithm converged.	0,29	0,89	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	12	2,0	1,22		Algorithm converged.	0,56	2,65	0,004		Algorithm converged.	-0,013	0,021	1,21		Algorithm converged.	0,56	2,60	0,6230		0,83		Algorithm converged.	0,39	1,77
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALOPECIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLISTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	DERMATITIS ACNEIFORM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE GENERALISED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXFOLIATIVE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NIGHT SWEATS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOCLASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ONYCHOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOMADESIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	3	1,1	2,12		Algorithm converged.	0,52	8,56	0,012		Algorithm converged.	-0,010	0,034		2,09		Algorithm converged.	0,53	8,28	0,2927		0,48		Algorithm converged.	0,12	1,89
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	2	0,2	4,61		Algorithm converged.	0,99	21,38	0,008		Algorithm converged.	0,001	0,015		4,57		Algorithm converged.	0,99	21,10	0,0515		0,22		Algorithm converged.	0,05	1,01
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	1	0,2	5,23		Algorithm converged.	0,61	44,86	0,007		Algorithm converged.	-0,001	0,015		5,19		Algorithm converged.	0,61	44,28	0,1323		0,19		Algorithm converged.	0,02	1,64
	PHOTOSENSITIVITY REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PSORIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008		4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008		1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	RASH MACULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH MACULO-PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SCAR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	SKIN TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SKIN ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOXIC EPIDERMAL NECROLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE				NE	NE
	TOXIC SKIN ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-				NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE				NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE				NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-				NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST RECONSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	5	1,8	1,70		Algorithm converged.	0,55	5,25	0,012		Algorithm converged.	-0,014	0,039		1,67		Algorithm converged.	0,55	5,05	0,3604		0,60		Algorithm converged.	0,20	1,80
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	34	3,8	0,47		Algorithm converged.	0,26	0,85	-0,020		Algorithm converged.	-0,035	-0,004		0,48		Algorithm converged.	0,27	0,86	0,0137		2,09		Algorithm converged.	1,16	3,76
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	17	2,8	0,85		Algorithm converged.	0,42	1,74	-0,004		Algorithm converged.	-0,022	0,014		0,85		Algorithm converged.	0,43	1,72	0,6593		1,17		Algorithm converged.	0,58	2,35
	AXILLARY VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,004		Algorithm converged.	-0,011	0,002		0,34		Algorithm converged.	0,07	1,67	0,1840		2,95		Algorithm converged.	0,60	14,59
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	2	0,7	3,74		Algorithm converged.	0,77	18,15	0,020		Algorithm converged.	-0,003	0,042		3,66		Algorithm converged.	0,77	17,47	0,1034		0,27		Algorithm converged.	0,06	1,30
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	19	2,1	0,42		Algorithm converged.	0,18	0,97	-0,012		Algorithm converged.	-0,023	-0,001		0,43		Algorithm converged.	0,19	0,97	0,0425		2,34		Algorithm converged.	1,03	5,31
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	11	1,8	0,66		Algorithm converged.	0,25	1,70	-0,006		Algorithm converged.	-0,020	0,008		0,66		Algorithm converged.	0,26	1,69	0,3874		1,51		Algorithm converged.	0,59	3,88
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	4	0,4	0,51		Algorithm converged.	0,09	2,77	-0,002		Algorithm converged.	-0,007	0,003		0,51		Algorithm converged.	0,09	2,77	0,4333		1,97		Algorithm converged.	0,36	10,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JUGULAR VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOSTATIC HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPERIOR VENA CAVA OCCLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOPHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479			2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR345_S1.xls
05MAY2022 16:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	419	23,5	1822	100,0	388	21,3	1,14		Algorithm converged.	0,97	1,33	0,022		Algorithm converged.	-0,005	0,049		1,10		Algorithm converged.	0,98	1,25	0,1126		0,91		Algorithm converged.	0,80	1,02
	AGRANULOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	n/a	1783	100,0	119	6,7	1822	100,0	86	4,7	1,44		Algorithm converged.	1,09	1,92	0,020		Algorithm converged.	0,004	0,035		1,41		Algorithm converged.	1,08	1,85	0,0118		0,71		Algorithm converged.	0,54	0,93
	BONE MARROW FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE NEUTROPENIA	n/a	1783	100,0	152	8,5	1822	100,0	140	7,7	1,12		Algorithm converged.	0,88	1,42	0,008		Algorithm converged.	-0,009	0,026	1,11		Algorithm converged.	0,89	1,38	0,3550		0,90		Algorithm converged.	0,72	1,12
	GRANULOCYTOPENIA	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	HAEMATOTOXICITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOLYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	IRON DEFICIENCY ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	LEUKOCYTOSIS	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEUKOPENIA	n/a	1783	100,0	60	3,4	1822	100,0	65	3,6	0,94		Algorithm converged.	0,66	1,35	-0,002		Algorithm converged.	-0,014	0,010	0,94		Algorithm converged.	0,67	1,33	0,7399		1,06		Algorithm converged.	0,75	1,50
	LYMPHOPENIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	MYELOSUPPRESSION	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	NEUTROPENIA	n/a	1783	100,0	129	7,2	1822	100,0	133	7,3	0,99		Algorithm converged.	0,77	1,27	-0,001		Algorithm converged.	-0,018	0,016	0,99		Algorithm converged.	0,78	1,25	0,9404		1,01		Algorithm converged.	0,80	1,27
	THROMBOCYTOPENIA	n/a	1783	100,0	12	0,7	1822	100,0	15	0,8	0,82		Algorithm converged.	0,38	1,75	-0,002		Algorithm converged.	-0,007	0,004	0,82		Algorithm converged.	0,38	1,74	0,6015		1,22		Algorithm converged.	0,57	2,61
CARDIAC DISORDER	-Total	n/a	1783	100,0	23	1,3	1822	100,0	22	1,2	1,07		Algorithm converged.	0,59	1,93	0,001		Algorithm converged.	-0,006	0,008	1,07		Algorithm converged.	0,60	1,91	0,8235		0,94		Algorithm converged.	0,52	1,67
	ACUTE CORONARY SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANGINA PECTORIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL FIBRILLATION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	ATRIAL THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE	n/a	1783	100,0	11	0,6	1822	100,0	7	0,4	1,61		Algorithm converged.	0,62	4,16	0,002		Algorithm converged.	-0,002	0,007	1,61		Algorithm converged.	0,62	4,13	0,3261		0,62		Algorithm converged.	0,24	1,60
	CARDIAC FAILURE CONGESTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSIVE CARDIOMYOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TACHYCARDIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA PAROXYSMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRICUSPID VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PYLORIC STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,000	0,20		Algorithm converged.	0,02	1,75	0,1470		4,89		Algorithm converged.	0,57	41,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTERNAL EAR INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOACUSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VERTIGO	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VESTIBULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
ENDOCRINE DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GOITRE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THYROID DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EYE DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARACT	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DRY EYE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LACRIMATION INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RETINAL DETACHMENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RETINAL VASCULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS FLOATERS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	263	14,8	1822	100,0	163	8,9	1,76		Algorithm converged.	1,43	2,17	0,058		Algorithm converged.	0,037	0,079	1,65		Algorithm converged.	1,37	1,98	<.0001		0,61		Algorithm converged.	0,50	0,73
	ABDOMINAL PAIN	n/a	1783	100,0	9	0,5	1822	100,0	9	0,5	1,02		Algorithm converged.	0,40	2,58	0,000		Algorithm converged.	-0,004	0,005	1,02		Algorithm converged.	0,41	2,57	0,9633		0,98		Algorithm converged.	0,39	2,46
	ABDOMINAL PAIN UPPER	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISSURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL FISTULA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APHTHOUS ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COLITIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS ISCHAEMIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONSTIPATION	n/a	1783	100,0	9	0,5	1822	100,0	6	0,3	1,54		Algorithm converged.	0,55	4,32	0,002		Algorithm converged.	-0,002	0,006	1,53		Algorithm converged.	0,55	4,30	0,4168		0,65		Algorithm converged.	0,23	1,83
	DENTAL CARIES	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	n/a	1783	100,0	165	9,3	1822	100,0	71	3,9	2,51		Algorithm converged.	1,89	3,35	0,054		Algorithm converged.	0,037	0,070	2,37		Algorithm converged.	1,81	3,11	<.0001		0,42		Algorithm converged.	0,32	0,55
	DRY MOUTH	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DUODENAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUODENAL ULCER HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTERITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ENTEROCOLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL TOXICITY	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	GLOSSITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHOIDAL HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHOIDS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INGUINAL HERNIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTUSSUSCEPTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOOSE TOOTH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MOUTH ULCERATION	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAUSEA	n/a	1783	100,0	36	2,0	1822	100,0	43	2,4	0,85		Algorithm converged.	0,54	1,33	-0,003		Algorithm converged.	-0,013	0,006	0,86		Algorithm converged.	0,55	1,33	0,4849		1,17		Algorithm converged.	0,75	1,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	n/a	1783	100,0	38	2,1	1822	100,0	18	1,0	2,18		Algorithm converged.	1,24	3,84	0,011		Algorithm converged.	0,003	0,020	2,16		Algorithm converged.	1,24	3,77	0,0068		0,46		Algorithm converged.	0,27	0,81
	SUBILEUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH DEVELOPMENT DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VOMITING	n/a	1783	100,0	30	1,7	1822	100,0	33	1,8	0,93		Algorithm converged.	0,56	1,53	-0,001		Algorithm converged.	-0,010	0,007	0,93		Algorithm converged.	0,57	1,52	0,7683		1,08		Algorithm converged.	0,66	1,76
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	125	7,0	1822	100,0	122	6,7	1,05		Algorithm converged.	0,81	1,36	0,003		Algorithm converged.	-0,013	0,020	1,05		Algorithm converged.	0,82	1,33	0,7085		0,96		Algorithm converged.	0,75	1,22
	ASTHENIA	n/a	1783	100,0	21	1,2	1822	100,0	34	1,9	0,63		Algorithm converged.	0,36	1,08	-0,007		Algorithm converged.	-0,015	0,001	0,63		Algorithm converged.	0,37	1,08	0,0949		1,58		Algorithm converged.	0,92	2,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	CHILLS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTRAVASATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FACIAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FATIGUE	n/a	1783	100,0	69	3,9	1822	100,0	49	2,7	1,46		Algorithm converged.	1,00	2,11	0,012		Algorithm converged.	0,000	0,023	1,44		Algorithm converged.	1,00	2,06	0,0477		0,69		Algorithm converged.	0,48	1,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	GENERALISED OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INFLUENZA LIKE ILLNESS	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION SITE EXTRAVASATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INJECTION SITE EXTRAVASATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MALAISE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	MUCOSAL DRYNESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878			0,98		Algorithm converged.	0,06	15,63
	MUCOSAL INFLAMMATION	n/a	1783	100,0	23	1,3	1822	100,0	12	0,7	1,97		Algorithm converged.	0,98	3,97	0,006		Algorithm converged.	0,000	0,013		1,96		Algorithm converged.	0,98	3,92	0,0580			0,51		Algorithm converged.	0,25	1,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OEDEMA PERIPHERAL	n/a	1783	100,0	0	0,0	1822	100,0	5	0,3	0,00		Algorithm converged.	0,00	NE	-0,003	*	WARNING: The relative Hessian convergence criterion of 51.704547935 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAIN	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYREXIA	n/a	1783	100,0	8	0,4	1822	100,0	12	0,7	0,68		Algorithm converged.	0,28	1,67	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,28	1,66	0,3991		1,47		Algorithm converged.	0,60	3,58
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3	1,02		Algorithm converged.	0,33	3,17	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,16	0,9701		0,98		Algorithm converged.	0,32	3,03
	CHOLANGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG-INDUCED LIVER INJURY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FAILURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FUNCTION ABNORMAL	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	HYPERTRANSAMINASAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	11	0,6	1822	100,0	14	0,8	0,80		Algorithm converged.	0,36	1,77	-0,002		Algorithm converged.	-0,007	0,004	0,80		Algorithm converged.	0,37	1,76	0,5846		1,25		Algorithm converged.	0,57	2,74
	ANAPHYLACTIC REACTION	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	HYPERSENSITIVITY	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5902		1,37		Algorithm converged.	0,44	4,31
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	117	6,6	1822	100,0	107	5,9	1,13		Algorithm converged.	0,86	1,48	0,007		Algorithm converged.	-0,009	0,023	1,12		Algorithm converged.	0,87	1,44	0,3916		0,89		Algorithm converged.	0,69	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ABSCESS LIMB	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	APPENDICITIS PERFORATED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BRONCHITIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CELLULITIS	n/a	1783	100,0	11	0,6	1822	100,0	11	0,6	1,02		Algorithm converged.	0,44	2,36	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,44	2,35	0,9594		0,98		Algorithm converged.	0,43	2,25
	CLOSTRIDIUM COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CLOSTRIDIUM DIFFICILE INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONJUNCTIVITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYSTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE RELATED INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	DEVICE RELATED SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA INFECTIOUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DISSEMINATED TUBERCULOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOCARDITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ENTEROCOLITIS INFECTIOUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHERICHIA INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FURUNCLE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROENTERITIS	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01
	GASTROENTERITIS VIRAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GINGIVITIS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	GROIN ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS B REACTIVATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES OPHTHALMIC	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES SIMPLEX	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES VIRUS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES ZOSTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTED LYMPHOCELE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOCALISED INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHANGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	n/a	1783	100,0	3	0,2	1822	100,0	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,004	0,002	0,61		Algorithm converged.	0,15	2,56	0,5025		1,63		Algorithm converged.	0,39	6,81
	MUCOSAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NASOPHARYNGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	ORAL CANDIDIASIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL FUNGAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OROPHARYNGITIS FUNGAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC INFLAMMATORY DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIODONTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PERITONSILLAR ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHARYNGITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PHARYNGITIS BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHLEBITIS INFECTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	n/a	1783	100,0	9	0,5	1822	100,0	10	0,5	0,92		Algorithm converged.	0,37	2,27	0,000		Algorithm converged.	-0,005	0,004	0,92		Algorithm converged.	0,37	2,26	0,8550		1,09		Algorithm converged.	0,44	2,67
	PNEUMONIA BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA PNEUMOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POST PROCEDURAL CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POSTOPERATIVE ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE WOUND INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSEUDOMONAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAS INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PYELONEPHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS ACUTE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SALPINGO-OOPHORITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERRATIA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SINUSITIS	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	7	0,4	0,44		Algorithm converged.	0,11	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2310		2,28		Algorithm converged.	0,59	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STAPHYLOCOCCAL SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STREPTOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TOOTH ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	URINARY TRACT INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	10	0,5	0,41		Algorithm converged.	0,13	1,30	-0,003		Algorithm converged.	-0,007	0,001	0,41		Algorithm converged.	0,13	1,30	0,1299		2,45		Algorithm converged.	0,77	7,79
	URINARY TRACT INFECTION ENTEROCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION PSEUDOMONAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR DEVICE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	VIRAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL CANDIDIASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	WOUND INFECTION STAPHYLOCOCCAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	29	1,6	1822	100,0	29	1,6	1,02		Algorithm converged.	0,61	1,72	0,000		Algorithm converged.	-0,008	0,009	1,02		Algorithm converged.	0,61	1,70	0,9338		0,98		Algorithm converged.	0,59	1,63
	ACCIDENTAL OVERDOSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FALL	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEMORAL NECK FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FOOT FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GRAFT THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAND FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HUMERUS FRACTURE	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	ILIUM FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFUSION RELATED REACTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIGAMENT SPRAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER LIMB FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOCONIOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RADIATION INJURY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	RADIATION SKIN INJURY	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIUS FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEROMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SPINAL COMPRESSION FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THERMAL BURN	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TIBIA FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOXICITY TO VARIOUS AGENTS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ULNA FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND COMPLICATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND DEHISCENCE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	WOUND HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WRIST FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INVESTIGATION	-Total	n/a	1783	100,0	208	11,7	1822	100,0	196	10,8	1,10		Algorithm converged.	0,89	1,35	0,009		Algorithm converged.	-0,012	0,030	1,08		Algorithm converged.	0,90	1,30	0,3875		0,92		Algorithm converged.	0,77	1,11
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	15	0,8	1822	100,0	14	0,8	1,10		Algorithm converged.	0,53	2,28	0,001		Algorithm converged.	-0,005	0,007	1,09		Algorithm converged.	0,53	2,26	0,8066		0,91		Algorithm converged.	0,44	1,89
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	8	0,4	1822	100,0	8	0,4	1,02		Algorithm converged.	0,38	2,73	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,38	2,72	0,9654		0,98		Algorithm converged.	0,37	2,60
	BLOOD ALKALINE PHOSPHATASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD CHOLESTEROL INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATININE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD GLUCOSE FLUCTUATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD GLUCOSE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD MAGNESIUM INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD POTASSIUM DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD PRESSURE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD TRIGLYCERIDES INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	C-REACTIVE PROTEIN INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EJECTION FRACTION DECREASED	n/a	1783	100,0	29	1,6	1822	100,0	30	1,6	0,99		Algorithm converged.	0,59	1,65	0,000		Algorithm converged.	-0,008	0,008	0,99		Algorithm converged.	0,60	1,64	0,9621		1,01		Algorithm converged.	0,61	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,005	0,001	0,34		Algorithm converged.	0,07	1,69	0,1868		2,94		Algorithm converged.	0,59	14,53
	GLOMERULAR FILTRATION RATE DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	HEPATIC ENZYME INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIPASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTE COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	LYMPHOCYTE COUNT INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	70	3,9	1822	100,0	76	4,2	0,94		Algorithm converged.	0,67	1,31	-0,002		Algorithm converged.	-0,015	0,010	0,94		Algorithm converged.	0,68	1,29	0,7088		1,06		Algorithm converged.	0,77	1,46
	NEUTROPHIL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	n/a	1783	100,0	16	0,9	1822	100,0	6	0,3	2,74		Algorithm converged.	1,07	7,02	0,006		Algorithm converged.	0,001	0,011	2,72		Algorithm converged.	1,07	6,95	0,0358		0,37		Algorithm converged.	0,14	0,94
	TRANSAMINASES INCREASED	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN T INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINE OUTPUT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WEIGHT DECREASED	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	WEIGHT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	76	4,3	1822	100,0	52	2,9	1,52		Algorithm converged.	1,06	2,17	0,014		Algorithm converged.	0,002	0,026	1,49		Algorithm converged.	1,06	2,11	0,0233		0,67		Algorithm converged.	0,47	0,95
	WHITE BLOOD CELL COUNT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	83	4,7	1822	100,0	40	2,2	2,18		Algorithm converged.	1,48	3,19	0,025		Algorithm converged.	0,013	0,036	2,12		Algorithm converged.	1,46	3,07	<.0001		0,47		Algorithm converged.	0,33	0,68
	DECREASED APPETITE	n/a	1783	100,0	15	0,8	1822	100,0	8	0,4	1,92		Algorithm converged.	0,81	4,55	0,004		Algorithm converged.	-0,001	0,009	1,92		Algorithm converged.	0,81	4,51	0,1363		0,52		Algorithm converged.	0,22	1,23
	DEHYDRATION	n/a	1783	100,0	16	0,9	1822	100,0	3	0,2	5,49		Algorithm converged.	1,60	18,87	0,007		Algorithm converged.	0,003	0,012	5,45		Algorithm converged.	1,59	18,67	0,0070		0,18		Algorithm converged.	0,05	0,63
	DIABETES MELLITUS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DIABETIC METABOLIC DECOMPENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROLYTE IMBALANCE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FAILURE TO THRIVE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FLUID RETENTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3	1,36		Algorithm converged.	0,47	3,94	0,001		Algorithm converged.	-0,003	0,005	1,36		Algorithm converged.	0,47	3,92	0,5661		0,73		Algorithm converged.	0,26	2,11
	HYPERKALAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERMAGNESAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTRIGLYCERIDAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	n/a	1783	100,0	27	1,5	1822	100,0	11	0,6	2,53		Algorithm converged.	1,25	5,12	0,009		Algorithm converged.	0,002	0,016	2,51		Algorithm converged.	1,25	5,04	0,0098		0,40		Algorithm converged.	0,20	0,80
	HYPOMAGNESAEMIA	n/a	1783	100,0	13	0,7	1822	100,0	1	<0.1	13,37		Algorithm converged.	1,75	102,35	0,007		Algorithm converged.	0,003	0,011	13,28		Algorithm converged.	1,74	101,44	0,0126		0,08		Algorithm converged.	0,01	0,57
	HYPONATRAEMIA	n/a	1783	100,0	5	0,3	1822	100,0	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,30	3,52	0,9727		0,98		Algorithm converged.	0,28	3,37
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	7	0,4	1822	100,0	3	0,2	2,39		Algorithm converged.	0,62	9,26	0,002		Algorithm converged.	-0,001	0,006	2,38		Algorithm converged.	0,62	9,21	0,2074		0,42		Algorithm converged.	0,11	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPROTEINAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOVOLAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TETANY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR LYSIS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	33	1,9	1822	100,0	55	3,0	0,61		Algorithm converged.	0,39	0,94	-0,012		Algorithm converged.	-0,022	-0,002	0,61		Algorithm converged.	0,40	0,94	0,0246		1,63		Algorithm converged.	1,06	2,50
	ARTHRALGIA	n/a	1783	100,0	13	0,7	1822	100,0	22	1,2	0,60		Algorithm converged.	0,30	1,20	-0,005		Algorithm converged.	-0,011	0,002	0,60		Algorithm converged.	0,31	1,19	0,1474		1,66		Algorithm converged.	0,84	3,28
	BACK PAIN	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	BONE PAIN	n/a	1783	100,0	2	0,1	1822	100,0	7	0,4	0,29		Algorithm converged.	0,06	1,40	-0,003		Algorithm converged.	-0,006	0,001	0,29		Algorithm converged.	0,06	1,40	0,1243		3,43		Algorithm converged.	0,71	16,46

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERVERTEBRAL DISC PROTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULAR WEAKNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL CHEST PAIN	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL PAIN	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5902		1,37		Algorithm converged.	0,44	4,31
	MYALGIA	n/a	1783	100,0	13	0,7	1822	100,0	21	1,2	0,63		Algorithm converged.	0,31	1,26	-0,004		Algorithm converged.	-0,011	0,002	0,63		Algorithm converged.	0,32	1,26	0,1924		1,58		Algorithm converged.	0,79	3,15
	PAIN IN EXTREMITY	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHEUMATOID ARTHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SJOGREN'S SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL OSTEOARTHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SPINAL STENOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BASAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST CANCER IN SITU	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MALIGNANT MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MONOCLONAL GAMMOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLARY THYROID CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SQUAMOUS CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UTERINE LEIOMYOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	74	4,2	1822	100,0	58	3,2	1,32		Algorithm converged.	0,93	1,87	0,010		Algorithm converged.	-0,003	0,022	1,30		Algorithm converged.	0,93	1,83	0,1234		0,77		Algorithm converged.	0,55	1,07
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARPAL TUNNEL SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CERVICAL RADICULOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	n/a	1783	100,0	0	0,0	1822	100,0	5	0,3	0,00		Algorithm converged.	0,00	NE	-0,003	*	WARNING: The relative Hessian convergence criterion of 51.704547935 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEADACHE	n/a	1783	100,0	3	0,2	1822	100,0	7	0,4	0,44		Algorithm converged.	0,11	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2310		2,28		Algorithm converged.	0,59	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERCOSTAL NEURALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LETHARGY	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIGRAINE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUROPATHY PERIPHERAL	n/a	1783	100,0	9	0,5	1822	100,0	12	0,7	0,77		Algorithm converged.	0,32	1,82	-0,002		Algorithm converged.	-0,006	0,003	0,77		Algorithm converged.	0,32	1,81	0,5451		1,30		Algorithm converged.	0,55	3,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARAESTHESIA	n/a	1783	100,0	8	0,4	1822	100,0	2	0,1	4,10		Algorithm converged.	0,87	19,34	0,003		Algorithm converged.	0,000	0,007	4,09		Algorithm converged.	0,87	19,22	0,0747		0,24		Algorithm converged.	0,05	1,15
	PERIPHERAL MOTOR NEUROPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PERIPHERAL SENSORY NEUROPATHY	n/a	1783	100,0	12	0,7	1822	100,0	9	0,5	1,36		Algorithm converged.	0,57	3,25	0,002		Algorithm converged.	-0,003	0,007	1,36		Algorithm converged.	0,58	3,23	0,4818		0,73		Algorithm converged.	0,31	1,74
	POLYNEUROPATHY	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	PRESYNCOPE	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	SCIATICA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	n/a	1783	100,0	18	1,0	1822	100,0	13	0,7	1,42		Algorithm converged.	0,69	2,90	0,003		Algorithm converged.	-0,003	0,009	1,41		Algorithm converged.	0,70	2,88	0,3383		0,71		Algorithm converged.	0,35	1,44
	THALAMIC INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSIENT ISCHAEMIC ATTACK	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
PRODUCT ISSUE	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	15	0,8	1822	100,0	10	0,5	1,54		Algorithm converged.	0,69	3,43	0,003		Algorithm converged.	-0,003	0,008	1,53		Algorithm converged.	0,69	3,40	0,2939		0,65		Algorithm converged.	0,29	1,45
	ANXIETY	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	EMOTIONAL DISTRESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INSOMNIA	n/a	1783	100,0	7	0,4	1822	100,0	2	0,1	3,59		Algorithm converged.	0,74	17,29	0,003		Algorithm converged.	0,000	0,006	3,58		Algorithm converged.	0,74	17,19	0,1116		0,28		Algorithm converged.	0,06	1,34
	MAJOR DEPRESSION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENTAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	REACTIVE PSYCHOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUICIDE ATTEMPT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	7	0,4	1822	100,0	7	0,4	1,02		Algorithm converged.	0,36	2,92	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,36	2,91	0,9676		0,98		Algorithm converged.	0,34	2,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE KIDNEY INJURY	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	BLADDER PROLAPSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSURIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEPHROLITHIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	n/a	1783	100,0	32	1,8	1822	100,0	37	2,0	0,88		Algorithm converged.	0,55	1,42	-0,002		Algorithm converged.	-0,011	0,007	0,88		Algorithm converged.	0,55	1,41	0,6054		1,13		Algorithm converged.	0,71	1,81
	AMENORRHOEA	n/a	1783	100,0	6	0,3	1822	100,0	9	0,5	0,68		Algorithm converged.	0,24	1,91	-0,002		Algorithm converged.	-0,006	0,003	0,68		Algorithm converged.	0,24	1,91	0,4656		1,47		Algorithm converged.	0,52	4,12

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST HAEMATOMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BREAST INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BREAST PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAVY MENSTRUAL BLEEDING	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUATION IRREGULAR	n/a	1783	100,0	19	1,1	1822	100,0	22	1,2	0,88		Algorithm converged.	0,48	1,63	-0,001		Algorithm converged.	-0,008	0,005	0,88		Algorithm converged.	0,48	1,62	0,6882		1,13		Algorithm converged.	0,62	2,09
	PREMATURE MENOPAUSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL DRYNESS	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	VULVOVAGINAL PRURITUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	23	1,3	1822	100,0	22	1,2	1,07		Algorithm converged.	0,59	1,93	0,001		Algorithm converged.	-0,006	0,008	1,07		Algorithm converged.	0,60	1,91	0,8235		0,94		Algorithm converged.	0,52	1,67
	ACUTE RESPIRATORY DISTRESS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APHONIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ASTHMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATELECTASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRONCHOSPASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARRH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	COUGH	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHONIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DYSPNOEA	n/a	1783	100,0	6	0,3	1822	100,0	10	0,5	0,61		Algorithm converged.	0,22	1,69	-0,002		Algorithm converged.	-0,006	0,002	0,61		Algorithm converged.	0,22	1,68	0,3425		1,63		Algorithm converged.	0,59	4,48
	EPISTAXIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG CONSOLIDATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONITIS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PULMONARY EMBOLISM	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	PULMONARY FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHINORRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHEEZING	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	63	3,5	1822	100,0	36	2,0	1,82		Algorithm converged.	1,20	2,75	0,016		Algorithm converged.	0,005	0,026	1,79		Algorithm converged.	1,19	2,68	0,0048		0,56		Algorithm converged.	0,37	0,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALOPECIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGIOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLISTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ACNEIFORM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS EXFOLIATIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE GENERALISED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRY SKIN	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ERYTHEMA	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	EXFOLIATIVE RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INGROWING NAIL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL DISCOLOURATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL DISORDER	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL TOXICITY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	NIGHT SWEATS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOCLASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOLYSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ONYCHOMADESIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	n/a	1783	100,0	20	1,1	1822	100,0	6	0,3	3,43		Algorithm converged.	1,38	8,57	0,008		Algorithm converged.	0,002	0,013	3,41		Algorithm converged.	1,37	8,46	0,0083		0,29		Algorithm converged.	0,12	0,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHOTOSENSITIVITY REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PRURITUS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	PSORIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	RASH MACULAR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH MACULO-PAPULAR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCAR PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN EXFOLIATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN IRRITATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN LESION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN TOXICITY	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	SKIN ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	TOXIC SKIN ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URTICARIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562358 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
SURGICAL AND MEDICAL PROCEDURE	-Total	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST RECONSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST TUMOUR EXCISION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	n/a	1783	100,0	39	2,2	1822	100,0	54	3,0	0,73		Algorithm converged.	0,48	1,11	-0,008		Algorithm converged.	-0,018	0,003	0,74		Algorithm converged.	0,49	1,11	0,1432		1,35		Algorithm converged.	0,90	2,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEEP VEIN THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	EMBOLISM	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HOT FLUSH	n/a	1783	100,0	4	0,2	1822	100,0	8	0,4	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,15	1,69	0,2721		1,96		Algorithm converged.	0,59	6,49
	HYPERTENSION	n/a	1783	100,0	23	1,3	1822	100,0	32	1,8	0,73		Algorithm converged.	0,43	1,25	-0,005		Algorithm converged.	-0,013	0,003	0,73		Algorithm converged.	0,43	1,25	0,2554		1,36		Algorithm converged.	0,80	2,32
	HYPOTENSION	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JUGULAR VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ORTHOSTATIC HYPOTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SUPERIOR VENA CAVA OCCLUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOPHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20
	VENOUS THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR3_S1.xls
05MAY2022 17:21

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	359	23,0	1601	87,9	337	21,0	1,12		Algorithm converged.	0,94	1,32	0,019		Algorithm converged.	-0,010	0,048	1,09		Algorithm converged.	0,96	1,24	0,1961	0,6325	0,92		Algorithm converged.	0,80	1,05
		>= 65	219	12,3	60	27,4	221	12,1	51	23,1	1,26		Algorithm converged.	0,82	1,94	0,043		Algorithm converged.	-0,038	0,124	1,19		Algorithm converged.	0,86	1,64	0,2979		0,84		Algorithm converged.	0,61	1,16
	AGRANULOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAEMIA	< 65	1564	87,7	93	5,9	1601	87,9	64	4,0	1,52		Algorithm converged.	1,10	2,10	0,019		Algorithm converged.	0,004	0,035	1,49		Algorithm converged.	1,09	2,03	0,0122	0,4856	0,67		Algorithm converged.	0,49	0,92
		>= 65	219	12,3	26	11,9	221	12,1	22	10,0	1,22		Algorithm converged.	0,67	2,22	0,019		Algorithm converged.	-0,039	0,077	1,19		Algorithm converged.	0,70	2,04	0,5196		0,84		Algorithm converged.	0,49	1,43
	BONE MARROW FAILURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003		1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	131	8,4	1601	87,9	115	7,2	1,18		Algorithm converged.	0,91	1,53	0,012		Algorithm converged.	-0,007	0,031		1,17		Algorithm converged.	0,92	1,48	0,2106	0,2960	0,86		Algorithm converged.	0,67	1,09
		>= 65	219	12,3	21	9,6	221	12,1	25	11,3	0,83		Algorithm converged.	0,45	1,53	-0,017		Algorithm converged.	-0,074	0,040		0,85		Algorithm converged.	0,49	1,47	0,5554		1,18		Algorithm converged.	0,68	2,04
	GRANULOCYTOPENIA	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004		1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HAEMATOTOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOLYTIC ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOCYTOSIS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LEUKOPENIA	< 65	1564	87,7	55	3,5	1601	87,9	57	3,6	0,99		Algorithm converged.	0,68	1,44	0,000		Algorithm converged.	-0,013	0,012	0,99		Algorithm converged.	0,69	1,42	0,9470	0,4433	1,01		Algorithm converged.	0,70	1,46
		>= 65	219	12,3	5	2,3	221	12,1	8	3,6	0,62		Algorithm converged.	0,20	1,93	-0,013		Algorithm converged.	-0,045	0,018	0,63		Algorithm converged.	0,21	1,90	0,4122		1,59		Algorithm converged.	0,53	4,77
	LYMPHOPENIA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	< 65	1564	87,7	112	7,2	1601	87,9	124	7,7	0,92		Algorithm converged.	0,70	1,20	-0,006		Algorithm converged.	-0,024	0,012	0,92		Algorithm converged.	0,72	1,18	0,5319	0,0774	1,08		Algorithm converged.	0,85	1,38
		>= 65	219	12,3	17	7,8	221	12,1	9	4,1	1,98		Algorithm converged.	0,86	4,55	0,037		Algorithm converged.	-0,007	0,081	1,91		Algorithm converged.	0,87	4,18	0,1077		0,52		Algorithm converged.	0,24	1,15
	THROMBOCYTOPENIA	< 65	1564	87,7	12	0,8	1601	87,9	11	0,7	1,12		Algorithm converged.	0,49	2,54	0,001		Algorithm converged.	-0,005	0,007	1,12		Algorithm converged.	0,49	2,52	0,7907	-	0,90		Algorithm converged.	0,40	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	4	1,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
CARDIAC DISORDER	-Total	< 65	1564	87,7	17	1,1	1601	87,9	15	0,9	1,16		Algorithm converged.	0,58	2,33	0,002		Algorithm converged.	-0,005	0,008	1,16		Algorithm converged.	0,58	2,31	0,6734	0,6518	0,86		Algorithm converged.	0,43	1,72
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	ACUTE CORONARY SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ANGINA PECTORIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ATRIAL FIBRILLATION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	< 65	1564	87,7	7	0,4	1601	87,9	5	0,3	1,44		Algorithm converged.	0,45	4,53	0,001		Algorithm converged.	-0,003	0,006	1,43		Algorithm converged.	0,46	4,51	0,5381	-	0,70		Algorithm converged.	0,22	2,19
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
	CARDIAC FAILURE CONGESTIVE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MITRAL VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MYOCARDIAL INFARCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,35	0,9868	-		0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013		1,01		Algorithm converged.	0,06	16,03	0,9949			0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA PAROXYSMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICUSPID VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PYLORIC STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3	0,20		Algorithm converged.	0,02	1,75	-0,002		Algorithm converged.	-0,005	0,001	0,20		Algorithm converged.	0,02	1,75	0,1474	-	4,88		Algorithm converged.	0,57	41,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTERNAL EAR INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOACUSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GOITRE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	THYROID DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATARACT	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY EYE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL VASCULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VITREOUS FLOATERS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	212	13,6	1601	87,9	135	8,4	1,70		Algorithm converged.	1,36	2,14	0,051		Algorithm converged.	0,029	0,073	1,61		Algorithm converged.	1,31	1,97	<.0001	0,5727	0,62		Algorithm converged.	0,51	0,76
		>= 65	219	12,3	51	23,3	221	12,1	28	12,7	2,09		Algorithm converged.	1,26	3,47	0,106		Algorithm converged.	0,035	0,177	1,84		Algorithm converged.	1,21	2,80	0,0046		0,54		Algorithm converged.	0,36	0,83
	ABDOMINAL PAIN	< 65	1564	87,7	8	0,5	1601	87,9	9	0,6	0,91		Algorithm converged.	0,35	2,36	-0,001		Algorithm converged.	-0,006	0,005	0,91		Algorithm converged.	0,35	2,35	0,8456	-	1,10		Algorithm converged.	0,43	2,84
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ABDOMINAL PAIN UPPER	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL FISSURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISTULA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHTHOUS ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS ISCHAEMIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DENTAL CARIES	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	< 65	1564	87,7	129	8,2	1601	87,9	53	3,3	2,63		Algorithm converged.	1,89	3,64	0,049		Algorithm converged.	0,033	0,066	2,49		Algorithm converged.	1,82	3,40	<.0001	0,5077	0,40		Algorithm converged.	0,29	0,55
		>= 65	219	12,3	36	16,4	221	12,1	18	8,1	2,22		Algorithm converged.	1,22	4,04	0,083		Algorithm converged.	0,022	0,144	2,02		Algorithm converged.	1,18	3,44	0,0100		0,50		Algorithm converged.	0,29	0,85
	DRY MOUTH	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTERITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL TOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	GLOSSITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHOIDAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INGUINAL HERNIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOOSE TOOTH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	MOUTH ULCERATION	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963459 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	NAUSEA	< 65	1564	87,7	30	1,9	1601	87,9	38	2,4	0,80		Algorithm converged.	0,50	1,30	-0,005		Algorithm converged.	-0,015	0,006	0,81		Algorithm converged.	0,50	1,30	0,3780	0,5296	1,24		Algorithm converged.	0,77	1,99	
		>= 65	219	12,3	6	2,7	221	12,1	5	2,3	1,22		Algorithm converged.	0,37	4,05	0,005		Algorithm converged.	-0,024	0,034	1,21		Algorithm converged.	0,38	3,91	0,7489		0,83		Algorithm converged.	0,26	2,67	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	< 65	1564	87,7	30	1,9	1601	87,9	15	0,9	2,07		Algorithm converged.	1,11	3,86	0,010		Algorithm converged.	0,002	0,018		2,05		Algorithm converged.	1,11	3,79	0,0226	0,7082	0,49		Algorithm converged.	0,26	0,90
		>= 65	219	12,3	8	3,7	221	12,1	3	1,4	2,76		Algorithm converged.	0,72	10,53	0,023		Algorithm converged.	-0,006	0,052		2,69		Algorithm converged.	0,72	10,01	0,1397		0,37		Algorithm converged.	0,10	1,38
	SUBILEUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH DEVELOPMENT DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOMITING	< 65	1564	87,7	25	1,6	1601	87,9	28	1,7	0,91		Algorithm converged.	0,53	1,57	-0,002		Algorithm converged.	-0,010	0,007	0,91		Algorithm converged.	0,54	1,56	0,7417	0,8846	1,09		Algorithm converged.	0,64	1,87
		>= 65	219	12,3	5	2,3	221	12,1	5	2,3	1,01		Algorithm converged.	0,29	3,54	0,000		Algorithm converged.	-0,028	0,028	1,01		Algorithm converged.	0,30	3,44	0,9884		0,99		Algorithm converged.	0,29	3,37
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	97	6,2	1601	87,9	94	5,9	1,06		Algorithm converged.	0,79	1,42	0,003		Algorithm converged.	-0,013	0,020	1,06		Algorithm converged.	0,80	1,39	0,6961	0,8732	0,95		Algorithm converged.	0,72	1,25
		>= 65	219	12,3	28	12,8	221	12,1	28	12,7	1,01		Algorithm converged.	0,58	1,77	0,001		Algorithm converged.	-0,061	0,063	1,01		Algorithm converged.	0,62	1,65	0,9710		0,99		Algorithm converged.	0,61	1,62
	ASTHENIA	< 65	1564	87,7	12	0,8	1601	87,9	22	1,4	0,55		Algorithm converged.	0,27	1,13	-0,006		Algorithm converged.	-0,013	0,001	0,56		Algorithm converged.	0,28	1,12	0,1027	0,5869	1,79		Algorithm converged.	0,89	3,61
		>= 65	219	12,3	9	4,1	221	12,1	12	5,4	0,75		Algorithm converged.	0,31	1,81	-0,013		Algorithm converged.	-0,053	0,027	0,76		Algorithm converged.	0,33	1,76	0,5176		1,32		Algorithm converged.	0,57	3,07
	AXILLARY PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHILLS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FACIAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FATIGUE	< 65	1564	87,7	51	3,3	1601	87,9	40	2,5	1,32		Algorithm converged.	0,86	2,00	0,008		Algorithm converged.	-0,004	0,019	1,31		Algorithm converged.	0,87	1,96	0,2008	0,3240	0,77		Algorithm converged.	0,51	1,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	18	8,2	221	12,1	9	4,1	2,11		Algorithm converged.	0,93	4,80	0,041		Algorithm converged.	-0,003	0,086	2,02		Algorithm converged.	0,93	4,39	0,0769		0,50		Algorithm converged.	0,23	1,08
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	GENERALISED OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA LIKE ILLNESS	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION SITE EXTRAVASATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MASS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MUCOSAL DRYNESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MUCOSAL INFLAMMATION	< 65	1564	87,7	20	1,3	1601	87,9	9	0,6	2,29		Algorithm converged.	1,04	5,05	0,007		Algorithm converged.	0,001	0,014	2,27		Algorithm converged.	1,04	4,98	0,0398	-	0,44		Algorithm converged.	0,20	0,96
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	< 65	1564	87,7	0	0,0	1601	87,9	5	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYREXIA	< 65	1564	87,7	8	0,5	1601	87,9	10	0,6	0,82		Algorithm converged.	0,32	2,08	-0,001		Algorithm converged.	-0,006	0,004	0,82		Algorithm converged.	0,32	2,07	0,6728	-	1,22		Algorithm converged.	0,48	3,09
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLANGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLELITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FUNCTION ABNORMAL	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERTRANSAMINASAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	11	0,7	1601	87,9	12	0,7	0,94		Algorithm converged.	0,41	2,13	0,000		Algorithm converged.	-0,006	0,005	0,94		Algorithm converged.	0,42	2,12	0,8784	-	1,07		Algorithm converged.	0,47	2,41

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAPHYLACTIC REACTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERSENSITIVITY	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	94	6,0	1601	87,9	90	5,6	1,07		Algorithm converged.	0,80	1,45	0,004		Algorithm converged.	-0,012	0,020	1,07		Algorithm converged.	0,81	1,42	0,6404	0,4666	0,94		Algorithm converged.	0,71	1,24
		>= 65	219	12,3	23	10,5	221	12,1	17	7,7	1,41		Algorithm converged.	0,73	2,72	0,028		Algorithm converged.	-0,026	0,082	1,37		Algorithm converged.	0,75	2,48	0,3078		0,73		Algorithm converged.	0,40	1,33
	ABDOMINAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABSCESS LIMB	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APPENDICITIS PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CATHETER SITE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	< 65	1564	87,7	9	0,6	1601	87,9	11	0,7	0,84		Algorithm converged.	0,35	2,02	-0,001		Algorithm converged.	-0,007	0,004	0,84		Algorithm converged.	0,35	2,02	0,6923	-	1,19		Algorithm converged.	0,50	2,87
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	CLOSTRIDIUM COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CLOSTRIDIUM DIFFICILE COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CLOSTRIDIUM DIFFICILE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONJUNCTIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	CYSTITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOCARDITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYSIPELAS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EYE INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FURUNCLE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE		NE	NE
	GASTROENTERITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005		4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013		1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROENTERITIS VIRAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GROIN ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES OPHTHALMIC	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES VIRUS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LARYNGITIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOCALISED INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LYMPHANGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUCOSAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAIL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL CANDIDIASIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARONYCHIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PELVIC INFLAMMATORY DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIODONTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERITONSILLAR ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	PHARYNGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,35	0,9868	-		0,98		Algorithm converged.	0,06	15,60						
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	PHARYNGITIS BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE WOUND INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PSEUDOMONAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PSEUDOMONAS INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PYELONEPHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RESPIRATORY TRACT INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERRATIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUSITIS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONSILLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	TOOTH INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	9	0,6	0,34		Algorithm converged.	0,09	1,26	-0,004		Algorithm converged.	-0,008	0,001	0,34		Algorithm converged.	0,09	1,26	0,1063	-	2,93		Algorithm converged.	0,79	10,81
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION ENTEROCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VASCULAR DEVICE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001		0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	VIRAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAL ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WOUND INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION STAPHYLOCOCCAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	26	1,7	1601	87,9	26	1,6	1,02		Algorithm converged.	0,59	1,77	0,000		Algorithm converged.	-0,008	0,009	1,02		Algorithm converged.	0,60	1,76	0,9323	-	0,98		Algorithm converged.	0,57	1,67
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACCIDENTAL OVERDOSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FALL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEMORAL NECK FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FOOT FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRAFT THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ILIUM FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INCISION SITE PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED REACTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LIGAMENT SPRAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER LIMB FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX TRAUMATIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RADIATION SKIN INJURY	< 65	1564	87,7	5	0,3	1601	87,9	7	0,4	0,73		Algorithm converged.	0,23	2,31	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5922	-	1,37		Algorithm converged.	0,43	4,30
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	RADIUS FRACTURE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECALL PHENOMENON	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THERMAL BURN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TIBIA FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULNA FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR ACCESS COMPLICATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND COMPLICATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND DEHISCENCE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
INVESTIGATION	-Total	< 65	1564	87,7	183	11,7	1601	87,9	169	10,6	1,12		Algorithm converged.	0,90	1,40	0,011		Algorithm converged.	-0,010	0,033	1,11		Algorithm converged.	0,91	1,35	0,3060	0,5407	0,90		Algorithm converged.	0,74	1,10
		>= 65	219	12,3	25	11,4	221	12,1	27	12,2	0,93		Algorithm converged.	0,52	1,65	-0,008		Algorithm converged.	-0,068	0,052	0,93		Algorithm converged.	0,56	1,56	0,7946		1,07		Algorithm converged.	0,64	1,78
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	14	0,9	1601	87,9	12	0,7	1,20		Algorithm converged.	0,55	2,59	0,001		Algorithm converged.	-0,005	0,008	1,19		Algorithm converged.	0,55	2,57	0,6505	-	0,84		Algorithm converged.	0,39	1,80
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	8	0,5	1601	87,9	8	0,5	1,02		Algorithm converged.	0,38	2,73	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,39	2,72	0,9626	-	0,98		Algorithm converged.	0,37	2,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD POTASSIUM DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	C-REACTIVE PROTEIN INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	EJECTION FRACTION DECREASED	< 65	1564	87,7	25	1,6	1601	87,9	23	1,4	1,11		Algorithm converged.	0,63	1,97	0,002		Algorithm converged.	-0,007	0,010		1,11		Algorithm converged.	0,63	1,95	0,7096	0,3278		0,90		Algorithm converged.	0,51	1,58
		>= 65	219	12,3	4	1,8	221	12,1	7	3,2	0,57		Algorithm converged.	0,16	1,97	-0,013		Algorithm converged.	-0,043	0,016		0,58		Algorithm converged.	0,17	1,94	0,3742			1,73		Algorithm converged.	0,51	5,84

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	6	0,4	0,17		Algorithm converged.	0,02	1,41	-0,003		Algorithm converged.	-0,006	0,000	0,17		Algorithm converged.	0,02	1,42	0,1014	-	5,86		Algorithm converged.	0,71	48,63
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLOMERULAR FILTRATION RATE DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36
	HEPATIC ENZYME INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER FUNCTION TEST INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOCYTE COUNT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LYMPHOCYTE COUNT INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	64	4,1	1601	87,9	68	4,2	0,96		Algorithm converged.	0,68	1,36	-0,002		Algorithm converged.	-0,015	0,012	0,96		Algorithm converged.	0,69	1,35	0,8271	0,6642	1,04		Algorithm converged.	0,74	1,45
		>= 65	219	12,3	6	2,7	221	12,1	8	3,6	0,75		Algorithm converged.	0,26	2,20	-0,009		Algorithm converged.	-0,042	0,024	0,76		Algorithm converged.	0,27	2,15	0,6002		1,32		Algorithm converged.	0,47	3,75
	NEUTROPHIL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PLATELET COUNT DECREASED	< 65	1564	87,7	12	0,8	1601	87,9	5	0,3	2,47		Algorithm converged.	0,87	7,02	0,005		Algorithm converged.	-0,001	0,010	2,46		Algorithm converged.	0,87	6,96	0,0906	-	0,41		Algorithm converged.	0,14	1,15
		>= 65	219	12,3	4	1,8	221	12,1	1	0,5	4,09		Algorithm converged.	0,45	36,92	0,014		Algorithm converged.	-0,006	0,034	4,04		Algorithm converged.	0,45	35,83	0,2103		0,25		Algorithm converged.	0,03	2,20
	TRANSAMINASES INCREASED	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN T INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE OUTPUT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WEIGHT DECREASED	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WEIGHT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	66	4,2	1601	87,9	46	2,9	1,49		Algorithm converged.	1,02	2,18	0,013		Algorithm converged.	0,001	0,026	1,47		Algorithm converged.	1,01	2,13	0,0417	0,8015	0,68		Algorithm converged.	0,47	0,99
		>= 65	219	12,3	10	4,6	221	12,1	6	2,7	1,71		Algorithm converged.	0,61	4,80	0,019		Algorithm converged.	-0,016	0,053	1,68		Algorithm converged.	0,62	4,55	0,3056		0,59		Algorithm converged.	0,22	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	55	3,5	1601	87,9	30	1,9	1,91		Algorithm converged.	1,22	2,99	0,016		Algorithm converged.	0,005	0,028	1,88		Algorithm converged.	1,21	2,91	0,0050	0,3230	0,53		Algorithm converged.	0,34	0,83
		>= 65	219	12,3	28	12,8	221	12,1	10	4,5	3,09		Algorithm converged.	1,46	6,54	0,083		Algorithm converged.	0,031	0,135	2,83		Algorithm converged.	1,41	5,68	0,0035		0,35		Algorithm converged.	0,18	0,71
	DECREASED APPETITE	< 65	1564	87,7	8	0,5	1601	87,9	6	0,4	1,37		Algorithm converged.	0,47	3,95	0,001		Algorithm converged.	-0,003	0,006	1,36		Algorithm converged.	0,47	3,92	0,5638	-	0,73		Algorithm converged.	0,25	2,11
		>= 65	219	12,3	7	3,2	221	12,1	2	0,9	3,62		Algorithm converged.	0,74	17,60	0,023		Algorithm converged.	-0,004	0,049	3,53		Algorithm converged.	0,74	16,81	0,1130		0,28		Algorithm converged.	0,06	1,35
	DEHYDRATION	< 65	1564	87,7	10	0,6	1601	87,9	3	0,2	3,43		Algorithm converged.	0,94	12,48	0,005		Algorithm converged.	0,000	0,009	3,41		Algorithm converged.	0,94	12,37	0,0619	-	0,29		Algorithm converged.	0,08	1,06
		>= 65	219	12,3	6	2,7	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIABETES MELLITUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	DIABETIC METABOLIC DECOMPENSATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROLYTE IMBALANCE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAILURE TO THRIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	< 65	1564	87,7	6	0,4	1601	87,9	4	0,2	1,54		Algorithm converged.	0,43	5,46	0,001		Algorithm converged.	-0,003	0,005	1,54		Algorithm converged.	0,43	5,43	0,5058	-	0,65		Algorithm converged.	0,18	2,30
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	HYPERKALAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERMAGNESAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPOCALCAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	< 65	1564	87,7	19	1,2	1601	87,9	7	0,4	2,80		Algorithm converged.	1,17	6,68	0,008		Algorithm converged.	0,001	0,014	2,78		Algorithm converged.	1,17	6,59	0,0204	0,6711	0,36		Algorithm converged.	0,15	0,85
		>= 65	219	12,3	8	3,7	221	12,1	4	1,8	2,06		Algorithm converged.	0,61	6,93	0,018		Algorithm converged.	-0,012	0,049	2,02		Algorithm converged.	0,62	6,61	0,2457		0,50		Algorithm converged.	0,15	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPOMAGNESAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	11	5,0	221	12,1	1	0,5	11,63		Algorithm converged.	1,49	90,91	0,046		Algorithm converged.	0,015	0,076	11,10		Algorithm converged.	1,45	85,25	0,0207		0,09		Algorithm converged.	0,01	0,69	
	HYPONATRAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57	
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	6	0,4	1601	87,9	3	0,2	2,05		Algorithm converged.	0,51	8,22	0,002		Algorithm converged.	-0,002	0,006	2,05		Algorithm converged.	0,51	8,17	0,3103	-	0,49		Algorithm converged.	0,12	1,95	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	HYPOPROTEINAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE	NE		Algorithm converged.	NE	NE
	HYPOVOLAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPOEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TETANY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR LYSIS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	< 65	1564	87,7	27	1,7	1601	87,9	48	3,0	0,57		Algorithm converged.	0,35	0,92	-0,013		Algorithm converged.	-0,023	-0,002	0,58		Algorithm converged.	0,36	0,92	0,0203	0,4983	1,74		Algorithm converged.	1,09	2,77
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	ARTHRALGIA	< 65	1564	87,7	11	0,7	1601	87,9	19	1,2	0,59		Algorithm converged.	0,28	1,24	-0,005		Algorithm converged.	-0,012	0,002	0,59		Algorithm converged.	0,28	1,24	0,1654	-	1,69		Algorithm converged.	0,81	3,53
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	BACK PAIN	< 65	1564	87,7	2	0,1	1601	87,9	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,005	0,001	0,41		Algorithm converged.	0,08	2,11	0,2854	-	2,44		Algorithm converged.	0,47	12,57
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BONE PAIN	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	INTERVERTEBRAL DISC PROTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULAR WEAKNESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL CHEST PAIN	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	< 65	1564	87,7	5	0,3	1601	87,9	5	0,3	1,02		Algorithm converged.	0,30	3,54	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,30	3,53	0,9705	-	0,98		Algorithm converged.	0,28	3,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYALGIA	< 65	1564	87,7	10	0,6	1601	87,9	20	1,2	0,51		Algorithm converged.	0,24	1,09	-0,006		Algorithm converged.	-0,013	0,001	0,51		Algorithm converged.	0,24	1,09	0,0824	-	1,95		Algorithm converged.	0,92	4,16
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	PAIN IN EXTREMITY	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RHEUMATOID ARTHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SJOGREN'S SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL OSTEOARTHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BASAL CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRADUCTAL PROLIFERATIVE BREAST LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LENTIGO MALIGNA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MENINGIOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONOCLONAL GAMMOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAPILLARY THYROID CANCER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	UTERINE LEIOMYOMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	54	3,5	1601	87,9	43	2,7	1,30		Algorithm converged.	0,86	1,95	0,008		Algorithm converged.	-0,004	0,020	1,29		Algorithm converged.	0,87	1,91	0,2121	0,9056	0,78		Algorithm converged.	0,52	1,15
		>= 65	219	12,3	20	9,1	221	12,1	15	6,8	1,38		Algorithm converged.	0,69	2,77	0,023		Algorithm converged.	-0,027	0,074	1,35		Algorithm converged.	0,71	2,56	0,3656		0,74		Algorithm converged.	0,39	1,41
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARPAL TUNNEL SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CERVICAL RADICULOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIZZINESS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERCOSTAL NEURALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	LETHARGY	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	MIGRAINE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	< 65	1564	87,7	7	0,4	1601	87,9	10	0,6	0,72		Algorithm converged.	0,27	1,88	-0,002		Algorithm converged.	-0,007	0,003	0,72		Algorithm converged.	0,27	1,88	0,4977	-	1,40		Algorithm converged.	0,53	3,66
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	< 65	1564	87,7	8	0,5	1601	87,9	2	0,1	4,11		Algorithm converged.	0,87	19,39	0,004		Algorithm converged.	0,000	0,008	4,09		Algorithm converged.	0,87	19,25	0,0743	-	0,24		Algorithm converged.	0,05	1,15
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL MOTOR NEUROPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIPHERAL SENSORY NEUROPATHY	< 65	1564	87,7	9	0,6	1601	87,9	5	0,3	1,85		Algorithm converged.	0,62	5,52	0,003		Algorithm converged.	-0,002	0,007	1,84		Algorithm converged.	0,62	5,49	0,2722	-	0,54		Algorithm converged.	0,18	1,62
		>= 65	219	12,3	3	1,4	221	12,1	4	1,8	0,75		Algorithm converged.	0,17	3,41	-0,004		Algorithm converged.	-0,028	0,019	0,76		Algorithm converged.	0,17	3,34	0,7131		1,32		Algorithm converged.	0,30	5,83
	POLYNEUROPATHY	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PRESYNCOPE	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCIATICA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	< 65	1564	87,7	9	0,6	1601	87,9	12	0,7	0,77		Algorithm converged.	0,32	1,82	-0,002		Algorithm converged.	-0,007	0,004	0,77		Algorithm converged.	0,32	1,82	0,5476	0,0082	1,30		Algorithm converged.	0,55	3,08
		>= 65	219	12,3	9	4,1	221	12,1	1	0,5	9,43		Algorithm converged.	1,18	75,07	0,037		Algorithm converged.	0,009	0,064	9,08		Algorithm converged.	1,16	71,08	0,0356		0,11		Algorithm converged.	0,01	0,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THALAMIC INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PRODUCT ISSUE	-Total	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE DISLOCATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE EXTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	12	0,8	1601	87,9	8	0,5	1,54		Algorithm converged.	0,63	3,78	0,003		Algorithm converged.	-0,003	0,008	1,54		Algorithm converged.	0,63	3,75	0,3460	-	0,65		Algorithm converged.	0,27	1,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	ANXIETY	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMOTIONAL DISTRESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	< 65	1564	87,7	6	0,4	1601	87,9	2	0,1	3,08		Algorithm converged.	0,62	15,28	0,003		Algorithm converged.	-0,001	0,006	3,07		Algorithm converged.	0,62	15,19	0,1690	-	0,33		Algorithm converged.	0,07	1,61
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MAJOR DEPRESSION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	MENTAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	REACTIVE PSYCHOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUICIDE ATTEMPT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE KIDNEY INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	3	1,4	0,67		Algorithm converged.	0,11	4,05	-0,004		Algorithm converged.	-0,024	0,015	0,67		Algorithm converged.	0,11	3,99	0,6624		1,49		Algorithm converged.	0,25	8,81
	BLADDER PROLAPSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSURIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEPHROLITHIASIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL FAILURE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	URINARY TRACT OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	< 65	1564	87,7	32	2,0	1601	87,9	36	2,2	0,91		Algorithm converged.	0,56	1,47	-0,002		Algorithm converged.	-0,012	0,008	0,91		Algorithm converged.	0,57	1,46	0,6945	-	1,10		Algorithm converged.	0,69	1,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	AMENORRHOEA	< 65	1564	87,7	6	0,4	1601	87,9	9	0,6	0,68		Algorithm converged.	0,24	1,92	-0,002		Algorithm converged.	-0,007	0,003	0,68		Algorithm converged.	0,24	1,91	0,4675	-	1,47		Algorithm converged.	0,52	4,11
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAVY MENSTRUAL BLEEDING	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENSTRUATION IRREGULAR	< 65	1564	87,7	19	1,2	1601	87,9	22	1,4	0,88		Algorithm converged.	0,48	1,64	-0,002		Algorithm converged.	-0,009	0,006	0,88		Algorithm converged.	0,48	1,63	0,6921	-	1,13		Algorithm converged.	0,61	2,08
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PREMATURE MENOPAUSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DRYNESS	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVOVAGINAL PRURITUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	18	1,2	1601	87,9	13	0,8	1,42		Algorithm converged.	0,69	2,91	0,003		Algorithm converged.	-0,003	0,010	1,42		Algorithm converged.	0,70	2,88	0,3356	0,1512	0,71		Algorithm converged.	0,35	1,43
		>= 65	219	12,3	5	2,3	221	12,1	9	4,1	0,55		Algorithm converged.	0,18	1,67	-0,018		Algorithm converged.	-0,051	0,015	0,56		Algorithm converged.	0,19	1,65	0,2923		1,78		Algorithm converged.	0,61	5,24
	ACUTE RESPIRATORY DISTRESS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APHONIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASTHMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHOSPASM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARRH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	COUGH	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHONIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	1	0,5	221	12,1	4	1,8	0,25		Algorithm converged.	0,03	2,24	-0,014		Algorithm converged.	-0,033	0,006	0,25		Algorithm converged.	0,03	2,24	0,2163		3,96		Algorithm converged.	0,45	35,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPISTAXIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PULMONARY EMBOLISM	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PULMONARY FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RHINORRHOEA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	WHEEZING	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	59	3,8	1601	87,9	29	1,8	2,13		Algorithm converged.	1,35	3,33	0,020		Algorithm converged.	0,008	0,031	2,08		Algorithm converged.	1,34	3,23	0,0011	0,0458	0,48		Algorithm converged.	0,31	0,74
		>= 65	219	12,3	4	1,8	221	12,1	7	3,2	0,57		Algorithm converged.	0,16	1,97	-0,013		Algorithm converged.	-0,043	0,016	0,58		Algorithm converged.	0,17	1,94	0,3742		1,73		Algorithm converged.	0,51	5,84
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALOPECIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BLISTER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DERMATITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005		4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DERMATITIS ACNEIFORM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2	0,68		Algorithm converged.	0,11	4,09	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,08	0,6753	-	1,47		Algorithm converged.	0,25	8,76
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	EXFOLIATIVE RASH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	INGROWING NAIL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL BED INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISCOLOURATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NAIL TOXICITY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	NIGHT SWEATS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276381 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ONYCHOCLASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ONYCHOMADESIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	< 65	1564	87,7	17	1,1	1601	87,9	4	0,2	4,39		Algorithm converged.	1,47	13,07	0,008		Algorithm converged.	0,003	0,014	4,35		Algorithm converged.	1,47	12,90	0,0080	-	0,23		Algorithm converged.	0,08	0,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	PHOTOSENSITIVITY REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE						
	PSORIASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE						
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	RASH	< 65	1564	87,7	7	0,4	1601	87,9	6	0,4	1,20		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,004	0,005	1,19		Algorithm converged.	0,40	3,55	0,7492	-	0,84		Algorithm converged.	0,28	2,49						
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH MACULAR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULO-PAPULAR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SCAR PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN IRRITATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN TOXICITY	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC SKIN ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URTICARIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SURGICAL AND MEDICAL PROCEDURE	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST RECONSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	< 65	1564	87,7	27	1,7	1601	87,9	44	2,7	0,62		Algorithm converged.	0,38	1,01	-0,010		Algorithm converged.	-0,021	0,000	0,63		Algorithm converged.	0,39	1,01	0,0546	0,1722	1,59		Algorithm converged.	0,99	2,56
		>= 65	219	12,3	12	5,5	221	12,1	10	4,5	1,22		Algorithm converged.	0,52	2,89	0,010		Algorithm converged.	-0,031	0,050	1,21		Algorithm converged.	0,53	2,74	0,6466		0,83		Algorithm converged.	0,36	1,87
	AXILLARY VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEEP VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMBOLISM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	< 65	1564	87,7	4	0,3	1601	87,9	8	0,5	0,51		Algorithm converged.	0,15	1,70	-0,002		Algorithm converged.	-0,007	0,002	0,51		Algorithm converged.	0,15	1,70	0,2733	-	1,95		Algorithm converged.	0,59	6,48
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	< 65	1564	87,7	17	1,1	1601	87,9	25	1,6	0,69		Algorithm converged.	0,37	1,29	-0,005		Algorithm converged.	-0,013	0,003	0,70		Algorithm converged.	0,38	1,28	0,2461	0,7311	1,44		Algorithm converged.	0,78	2,65
		>= 65	219	12,3	6	2,7	221	12,1	7	3,2	0,86		Algorithm converged.	0,28	2,60	-0,004		Algorithm converged.	-0,036	0,027	0,86		Algorithm converged.	0,30	2,53	0,7913		1,16		Algorithm converged.	0,39	3,38
	HYPOTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	JUGULAR VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LYMPHOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOSTATIC HYPOTENSION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCLAVIAN VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPERIOR VENA CAVA OCCLUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENOUS THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR3_S1.xls
05MAY2022 17:21

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	77	29,4	252	13,8	62	24,6	1,28		Algorithm converged.	0,86	1,89	0,048		Algorithm converged.	-0,029	0,124	1,19		Algorithm converged.	0,90	1,59	0,2236	0,0055	0,84		Algorithm converged.	0,63	1,11
		Western Europe	814	45,7	155	19,0	824	45,2	176	21,4	0,87		Algorithm converged.	0,68	1,10	-0,023		Algorithm converged.	-0,062	0,016	0,89		Algorithm converged.	0,74	1,08	0,2434		1,12		Algorithm converged.	0,92	1,36
		Asia Pacific	482	27,0	134	27,8	517	28,4	122	23,6	1,25		Algorithm converged.	0,94	1,66	0,042		Algorithm converged.	-0,012	0,096	1,18		Algorithm converged.	0,95	1,46	0,1289		0,85		Algorithm converged.	0,69	1,05
		Latin America	42	2,4	8	19,0	45	2,5	8	17,8	1,09		Algorithm converged.	0,37	3,22	0,013		Algorithm converged.	-0,150	0,176	1,07		Algorithm converged.	0,44	2,60	0,8786		0,93		Algorithm converged.	0,39	2,26
		Other	183	10,3	45	24,6	184	10,1	20	10,9	2,67		Algorithm converged.	1,51	4,74	0,137		Algorithm converged.	0,060	0,214	2,26		Algorithm converged.	1,39	3,68	0,0010		0,44		Algorithm converged.	0,27	0,72
	AGRANULOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	USA/Canada	262	14,7	41	15,6	252	13,8	26	10,3	1,61		Algorithm converged.	0,95	2,73	0,053		Algorithm converged.	-0,005	0,111	1,52		Algorithm converged.	0,96	2,40	0,0759	-	0,66		Algorithm converged.	0,42	1,04
		Western Europe	814	45,7	31	3,8	824	45,2	32	3,9	0,98		Algorithm converged.	0,59	1,62	-0,001		Algorithm converged.	-0,019	0,018	0,98		Algorithm converged.	0,60	1,59	0,9370		1,02		Algorithm converged.	0,63	1,66

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	38	7,9	517	28,4	22	4,3	1,93		Algorithm converged.	1,12	3,31	0,036		Algorithm converged.	0,007	0,066	1,85		Algorithm converged.	1,11	3,09	0,0178		0,54		Algorithm converged.	0,32	0,90
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	6	3,3	184	10,1	4	2,2	1,53		Algorithm converged.	0,42	5,50	0,011		Algorithm converged.	-0,022	0,044	1,51		Algorithm converged.	0,43	5,26	0,5189		0,66		Algorithm converged.	0,19	2,31
	BONE MARROW FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	13	5,0	252	13,8	18	7,1	0,68		Algorithm converged.	0,33	1,42	-0,022		Algorithm converged.	-0,063	0,019	0,69		Algorithm converged.	0,35	1,39	0,3022	-	1,44		Algorithm converged.	0,72	2,88
		Western Europe	814	45,7	71	8,7	824	45,2	76	9,2	0,94		Algorithm converged.	0,67	1,32	-0,005		Algorithm converged.	-0,033	0,023	0,95		Algorithm converged.	0,69	1,29	0,7229		1,06		Algorithm converged.	0,78	1,44
		Asia Pacific	482	27,0	56	11,6	517	28,4	43	8,3	1,45		Algorithm converged.	0,95	2,20	0,033		Algorithm converged.	-0,004	0,070	1,40		Algorithm converged.	0,96	2,04	0,0827		0,72		Algorithm converged.	0,49	1,04
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138	3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	9	4,9	184	10,1	2	1,1	4,71		Algorithm converged.	1,00	22,09	0,038		Algorithm converged.	0,004	0,073		4,52		Algorithm converged.	0,99	20,66	0,0514		0,22		Algorithm converged.	0,05	1,01
	GRANULOCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012		1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HAEMATOTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	IRON DEFICIENCY ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOPENIA	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028	1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
		Western Europe	814	45,7	16	2,0	824	45,2	29	3,5	0,55		Algorithm converged.	0,30	1,02	-0,016		Algorithm converged.	-0,031	0,000	0,56		Algorithm converged.	0,31	1,02	0,0582		1,79		Algorithm converged.	0,98	3,27
		Asia Pacific	482	27,0	26	5,4	517	28,4	28	5,4	1,00		Algorithm converged.	0,58	1,72	0,000		Algorithm converged.	-0,028	0,028	1,00		Algorithm converged.	0,59	1,67	0,9879		1,00		Algorithm converged.	0,60	1,69
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055	0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	12	6,6	184	10,1	3	1,6	4,23		Algorithm converged.	1,17	15,26	0,049		Algorithm converged.	0,009	0,090	4,02		Algorithm converged.	1,15	14,02	0,0289		0,25		Algorithm converged.	0,07	0,87
	LYMPHOPENIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	5	1,0	0,43		Algorithm converged.	0,08	2,21	-0,006		Algorithm converged.	-0,016	0,005	0,43		Algorithm converged.	0,08	2,20	0,3104		2,33		Algorithm converged.	0,45	11,96
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIA	USA/Canada	262	14,7	26	9,9	252	13,8	16	6,3	1,62		Algorithm converged.	0,85	3,11	0,036		Algorithm converged.	-0,011	0,083	1,56		Algorithm converged.	0,86	2,84	0,1435	-	0,64		Algorithm converged.	0,35	1,16
		Western Europe	814	45,7	50	6,1	824	45,2	59	7,2	0,85		Algorithm converged.	0,57	1,25	-0,010		Algorithm converged.	-0,034	0,014	0,86		Algorithm converged.	0,60	1,23	0,4092		1,17		Algorithm converged.	0,81	1,68
		Asia Pacific	482	27,0	30	6,2	517	28,4	39	7,5	0,81		Algorithm converged.	0,50	1,33	-0,013		Algorithm converged.	-0,045	0,018	0,83		Algorithm converged.	0,52	1,31	0,4122		1,21		Algorithm converged.	0,77	1,92
		Latin America	42	2,4	3	7,1	45	2,5	6	13,3	0,50		Algorithm converged.	0,12	2,14	-0,062		Algorithm converged.	-0,188	0,064	0,54		Algorithm converged.	0,14	2,01	0,3543		1,87		Algorithm converged.	0,50	6,99
		Other	183	10,3	20	10,9	184	10,1	13	7,1	1,61		Algorithm converged.	0,78	3,35	0,039		Algorithm converged.	-0,020	0,097	1,55		Algorithm converged.	0,79	3,02	0,2003		0,65		Algorithm converged.	0,33	1,26
	THROMBOCYTOPENIA	USA/Canada	262	14,7	6	2,3	252	13,8	6	2,4	0,96		Algorithm converged.	0,31	3,02	-0,001		Algorithm converged.	-0,027	0,025	0,96		Algorithm converged.	0,31	2,94	0,9456	-	1,04		Algorithm converged.	0,34	3,18
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004	0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
		Asia Pacific	482	27,0	3	0,6	517	28,4	3	0,6	1,07		Algorithm converged.	0,22	5,34	0,000		Algorithm converged.	-0,009	0,010	1,07		Algorithm converged.	0,22	5,29	0,9314		0,93		Algorithm converged.	0,19	4,60
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026	1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	12	1,5	824	45,2	10	1,2	1,22		Algorithm converged.	0,52	2,83	0,003		Algorithm converged.	-0,009	0,014	1,21		Algorithm converged.	0,53	2,80	0,6474		0,82		Algorithm converged.	0,36	1,89
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	4	2,2	184	10,1	3	1,6	1,35		Algorithm converged.	0,30	6,11	0,006		Algorithm converged.	-0,022	0,034	1,34		Algorithm converged.	0,30	5,91	0,6984		0,75		Algorithm converged.	0,17	3,29
	ACUTE CORONARY SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIAL FIBRILLATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ATRIAL THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE CONGESTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CORONARY ARTERY STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MITRAL VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUPRAVENTRICULAR TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA PAROXYSMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	TRICUSPID VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTERNAL EAR INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk										Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOACUSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VESTIBULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
ENDOCRINE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE			NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE			NE			Algorithm converged.	NE	NE
	GOITRE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EYE DISORDER	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARACT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY EYE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RETINAL VASCULAR DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VITREOUS FLOATERS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	52	19,8	252	13,8	24	9,5	2,35		Algorithm converged.	1,40	3,95	0,103		Algorithm converged.	0,043	0,164	2,08		Algorithm converged.	1,33	3,27	0,0014	-	0,48		Algorithm converged.	0,31	0,75
		Western Europe	814	45,7	137	16,8	824	45,2	94	11,4	1,57		Algorithm converged.	1,18	2,08	0,054		Algorithm converged.	0,021	0,088	1,48		Algorithm converged.	1,16	1,88	0,0018		0,68		Algorithm converged.	0,53	0,87
		Asia Pacific	482	27,0	56	11,6	517	28,4	38	7,4	1,66		Algorithm converged.	1,08	2,55	0,043		Algorithm converged.	0,006	0,079	1,58		Algorithm converged.	1,07	2,34	0,0223		0,63		Algorithm converged.	0,43	0,94
		Latin America	42	2,4	5	11,9	45	2,5	2	4,4	2,91		Algorithm converged.	0,53	15,87	0,075		Algorithm converged.	-0,040	0,190	2,68		Algorithm converged.	0,55	13,07	0,2231		0,37		Algorithm converged.	0,08	1,82
		Other	183	10,3	13	7,1	184	10,1	5	2,7	2,74		Algorithm converged.	0,96	7,84	0,044		Algorithm converged.	0,000	0,088	2,61		Algorithm converged.	0,95	7,18	0,0624		0,38		Algorithm converged.	0,14	1,05
	ABDOMINAL PAIN	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008	1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL PAIN UPPER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL FISSURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL FISTULA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHTHOUS ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	COLITIS ISCHAEMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	CONSTIPATION	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017		1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70	
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009		1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47	
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DENTAL CARIES	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	USA/Canada	262	14,7	41	15,6	252	13,8	9	3,6	5,01		Algorithm converged.	2,38	10,54	0,121		Algorithm converged.	0,071	0,170	4,38		Algorithm converged.	2,17	8,83	<.0001	-	0,23		Algorithm converged.	0,11	0,46
		Western Europe	814	45,7	82	10,1	824	45,2	47	5,7	1,85		Algorithm converged.	1,28	2,69	0,044		Algorithm converged.	0,018	0,070	1,77		Algorithm converged.	1,25	2,49	0,0012		0,57		Algorithm converged.	0,40	0,80
		Asia Pacific	482	27,0	33	6,8	517	28,4	13	2,5	2,85		Algorithm converged.	1,48	5,48	0,043		Algorithm converged.	0,017	0,070	2,72		Algorithm converged.	1,45	5,11	0,0018		0,37		Algorithm converged.	0,20	0,69
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	9	4,9	184	10,1	1	0,5	9,47		Algorithm converged.	1,19	75,49	0,044		Algorithm converged.	0,011	0,077	9,05		Algorithm converged.	1,16	70,70	0,0357		0,11		Algorithm converged.	0,01	0,86
	DRY MOUTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ENTERITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ENTEROCOLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	GASTRIC ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GLOSSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LOOSE TOOTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MOUTH ULCERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAUSEA	USA/Canada	262	14,7	5	1,9	252	13,8	8	3,2	0,59		Algorithm converged.	0,19	1,84	-0,013		Algorithm converged.	-0,040	0,015	0,60		Algorithm converged.	0,20	1,81	0,3662	-	1,66		Algorithm converged.	0,55	5,02
		Western Europe	814	45,7	17	2,1	824	45,2	23	2,8	0,74		Algorithm converged.	0,39	1,40	-0,007		Algorithm converged.	-0,022	0,008	0,75		Algorithm converged.	0,40	1,39	0,3587		1,34		Algorithm converged.	0,72	2,48
		Asia Pacific	482	27,0	12	2,5	517	28,4	10	1,9	1,29		Algorithm converged.	0,55	3,02	0,006		Algorithm converged.	-0,013	0,024	1,29		Algorithm converged.	0,56	2,95	0,5511		0,78		Algorithm converged.	0,34	1,78
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	ORAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	24	2,9	824	45,2	11	1,3	2,25		Algorithm converged.	1,09	4,61	0,016		Algorithm converged.	0,002	0,030	2,21		Algorithm converged.	1,09	4,48	0,0281		0,45		Algorithm converged.	0,22	0,92
		Asia Pacific	482	27,0	9	1,9	517	28,4	6	1,2	1,62		Algorithm converged.	0,57	4,59	0,007		Algorithm converged.	-0,008	0,022	1,61		Algorithm converged.	0,58	4,49	0,3634		0,62		Algorithm converged.	0,22	1,73

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812879 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VOMITING	USA/Canada	262	14,7	4	1,5	252	13,8	4	1,6	0,96		Algorithm converged.	0,24	3,89	-0,001		Algorithm converged.	-0,022	0,021		0,96		Algorithm converged.	0,24	3,80	0,9558	-	1,04		Algorithm converged.	0,26	4,11
		Western Europe	814	45,7	15	1,8	824	45,2	14	1,7	1,09		Algorithm converged.	0,52	2,26	0,001		Algorithm converged.	-0,011	0,014		1,08		Algorithm converged.	0,53	2,23	0,8255		0,92		Algorithm converged.	0,45	1,90
		Asia Pacific	482	27,0	10	2,1	517	28,4	10	1,9	1,07		Algorithm converged.	0,44	2,60	0,001		Algorithm converged.	-0,016	0,019		1,07		Algorithm converged.	0,45	2,55	0,8742		0,93		Algorithm converged.	0,39	2,22
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	4	2,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	22	8,4	252	13,8	22	8,7	0,96		Algorithm converged.	0,52	1,78	-0,003		Algorithm converged.	-0,052	0,045	0,96		Algorithm converged.	0,55	1,69	0,8926	-	1,04		Algorithm converged.	0,59	1,83
		Western Europe	814	45,7	79	9,7	824	45,2	78	9,5	1,03		Algorithm converged.	0,74	1,43	0,002		Algorithm converged.	-0,026	0,031	1,03		Algorithm converged.	0,76	1,38	0,8694		0,98		Algorithm converged.	0,72	1,31
		Asia Pacific	482	27,0	11	2,3	517	28,4	17	3,3	0,69		Algorithm converged.	0,32	1,48	-0,010		Algorithm converged.	-0,030	0,010	0,69		Algorithm converged.	0,33	1,47	0,3387		1,44		Algorithm converged.	0,68	3,04
		Latin America	42	2,4	3	7,1	45	2,5	1	2,2	3,38		Algorithm converged.	0,34	33,89	0,049		Algorithm converged.	-0,040	0,138	3,21		Algorithm converged.	0,35	29,71	0,3034		0,31		Algorithm converged.	0,03	2,88
		Other	183	10,3	10	5,5	184	10,1	4	2,2	2,60		Algorithm converged.	0,80	8,45	0,033		Algorithm converged.	-0,006	0,072	2,51		Algorithm converged.	0,80	7,87	0,1135		0,40		Algorithm converged.	0,13	1,25
	ASTHENIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	16	2,0	824	45,2	26	3,2	0,62		Algorithm converged.	0,33	1,16	-0,012		Algorithm converged.	-0,027	0,003	0,62		Algorithm converged.	0,34	1,15	0,1316		1,61		Algorithm converged.	0,87	2,97
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	AXILLARY PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHILLS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	DEVICE RELATED THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	FACE OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	FACIAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	FATIGUE	USA/Canada	262	14,7	14	5,3	252	13,8	13	5,2	1,04		Algorithm converged.	0,48	2,25	0,002		Algorithm converged.	-0,037	0,040		1,04		Algorithm converged.	0,50	2,16	0,9252	-		0,97		Algorithm converged.	0,46	2,01	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	39	4,8	824	45,2	26	3,2	1,54		Algorithm converged.	0,93	2,56	0,016		Algorithm converged.	-0,003	0,035		1,52		Algorithm converged.	0,93	2,47	0,0926			0,66		Algorithm converged.	0,40	1,07
		Asia Pacific	482	27,0	8	1,7	517	28,4	9	1,7	0,95		Algorithm converged.	0,36	2,49	-0,001		Algorithm converged.	-0,017	0,015		0,95		Algorithm converged.	0,37	2,45	0,9212			1,05		Algorithm converged.	0,41	2,70
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	7	3,8	184	10,1	1	0,5	7,28		Algorithm converged.	0,89	59,76	0,033		Algorithm converged.	0,003	0,063		7,04		Algorithm converged.	0,87	56,64	0,0666			0,14		Algorithm converged.	0,02	1,14
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662			1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GENERALISED OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFLUENZA LIKE ILLNESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION SITE EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MALAISE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MASS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL DRYNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	17	2,1	824	45,2	8	1,0	2,18		Algorithm converged.	0,93	5,07	0,011		Algorithm converged.	-0,001	0,023	2,15		Algorithm converged.	0,93	4,96	0,0721		0,46		Algorithm converged.	0,20	1,07
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,046	*	WARNING: The relative Hessian convergence criterion of 9.1448002085 is greater than the limit of 0.0001. The convergence is questionable.	-0,258	0,351	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PYREXIA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023		2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004		0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC CYTOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATIC FUNCTION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERTRANSAMINASAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	4	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	7	0,9	824	45,2	8	1,0	0,88		Algorithm converged.	0,32	2,45	-0,001		Algorithm converged.	-0,010	0,008	0,89		Algorithm converged.	0,32	2,43	0,8138		1,13		Algorithm converged.	0,41	3,10
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAPHYLACTIC REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6	0,61		Algorithm converged.	0,14	2,54	-0,002		Algorithm converged.	-0,009	0,004	0,61		Algorithm converged.	0,15	2,53	0,4938		1,65		Algorithm converged.	0,39	6,87
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	17	6,5	252	13,8	27	10,7	0,58		Algorithm converged.	0,31	1,09	-0,042		Algorithm converged.	-0,091	0,006		0,61		Algorithm converged.	0,34	1,08	0,0910	-	1,65		Algorithm converged.	0,92	2,95
		Western Europe	814	45,7	69	8,5	824	45,2	51	6,2	1,40		Algorithm converged.	0,96	2,04	0,023		Algorithm converged.	-0,002	0,048		1,37		Algorithm converged.	0,97	1,94	0,0771		0,73		Algorithm converged.	0,52	1,03
		Asia Pacific	482	27,0	26	5,4	517	28,4	26	5,0	1,08		Algorithm converged.	0,62	1,88	0,004		Algorithm converged.	-0,024	0,031		1,07		Algorithm converged.	0,63	1,82	0,7952		0,93		Algorithm converged.	0,55	1,58
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	5	2,7	184	10,1	3	1,6	1,69		Algorithm converged.	0,40	7,20	0,011		Algorithm converged.	-0,019	0,041		1,68		Algorithm converged.	0,41	6,91	0,4751		0,60		Algorithm converged.	0,14	2,46
	ABDOMINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS LIMB	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	APPENDICITIS PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BACTERIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	BREAST ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	CATHETER SITE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	USA/Canada	262	14,7	3	1,1	252	13,8	6	2,4	0,47		Algorithm converged.	0,12	1,92	-0,012		Algorithm converged.	-0,035	0,010	0,48		Algorithm converged.	0,12	1,90	0,2967	-	2,08		Algorithm converged.	0,53	8,22
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	5	1,0	517	28,4	3	0,6	1,80		Algorithm converged.	0,43	7,56	0,005		Algorithm converged.	-0,007	0,016	1,79		Algorithm converged.	0,43	7,44	0,4246		0,56		Algorithm converged.	0,13	2,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CYSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENDOCARDITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
	EYE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999	-	>999			Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	FURUNCLE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	GASTROENTERITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROENTERITIS VIRAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GINGIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GROIN ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES OPHTHALMIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES VIRUS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LOCALISED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.563 62484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MASTITIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUCOSAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASOPHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008		1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ORAL CANDIDIASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OTITIS MEDIA ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARONYCHIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC INFLAMMATORY DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	1	0,4	252	13,8	4	1,6	0,24		Algorithm converged.	0,03	2,14	-0,012		Algorithm converged.	-0,029	0,005	0,24		Algorithm converged.	0,03	2,14	0,2010	-	4,16		Algorithm converged.	0,47	36,95
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013	1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PSEUDOMONAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PSEUDOMONAS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE	NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00			Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SALPINGO-OOPHORITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SEPTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SERRATIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SOFT TISSUE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCUTANEOUS ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TOOTH ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	TOOTH INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	4	0,8	0,53		Algorithm converged.	0,10	2,93	-0,004		Algorithm converged.	-0,013	0,006	0,54		Algorithm converged.	0,10	2,91	0,4707		1,86		Algorithm converged.	0,34	10,13
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION ENTEROCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROSEPSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION STAPHYLOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	5	2,0	1,16		Algorithm converged.	0,35	3,84	0,003		Algorithm converged.	-0,022	0,028	1,15		Algorithm converged.	0,36	3,73	0,8108	-	0,87		Algorithm converged.	0,27	2,80
		Western Europe	814	45,7	14	1,7	824	45,2	14	1,7	1,01		Algorithm converged.	0,48	2,14	0,000		Algorithm converged.	-0,012	0,013	1,01		Algorithm converged.	0,49	2,11	0,9740		0,99		Algorithm converged.	0,47	2,06
		Asia Pacific	482	27,0	6	1,2	517	28,4	5	1,0	1,29		Algorithm converged.	0,39	4,26	0,003		Algorithm converged.	-0,010	0,016	1,29		Algorithm converged.	0,40	4,19	0,6751		0,78		Algorithm converged.	0,24	2,53
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	4	2,2	0,50		Algorithm converged.	0,09	2,75	-0,011		Algorithm converged.	-0,037	0,015	0,50		Algorithm converged.	0,09	2,71	0,4238		1,99		Algorithm converged.	0,37	10,73
	ACCIDENTAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	FALL	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE		NE				
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE				
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE				
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE				
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE				
	FEMORAL NECK FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE				

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FOOT FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAND FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
	ILIUM FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INCISION SITE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTENTIONAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JOINT DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIGAMENT SPRAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER LIMB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOCONIOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX TRAUMATIC	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION SKIN INJURY	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	RADIUS FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	RECALL PHENOMENON	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	SEROMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE		NE				
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	THERMAL BURN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TIBIA FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ULNA FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR ACCESS COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	USA/Canada	262	14,7	24	9,2	252	13,8	19	7,5	1,24		Algorithm converged.	0,66	2,32	0,016		Algorithm converged.	-0,032	0,064	1,21		Algorithm converged.	0,68	2,16	0,5080	-	0,82		Algorithm converged.	0,46	1,46
		Western Europe	814	45,7	80	9,8	824	45,2	99	12,0	0,80		Algorithm converged.	0,58	1,09	-0,022		Algorithm converged.	-0,052	0,008	0,82		Algorithm converged.	0,62	1,08	0,1571		1,22		Algorithm converged.	0,93	1,61
		Asia Pacific	482	27,0	98	20,3	517	28,4	72	13,9	1,58		Algorithm converged.	1,13	2,20	0,064		Algorithm converged.	0,017	0,111	1,46		Algorithm converged.	1,11	1,93	0,0076		0,68		Algorithm converged.	0,52	0,90
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	6	0,7	824	45,2	5	0,6	1,22		Algorithm converged.	0,37	4,00	0,001		Algorithm converged.	-0,007	0,009		1,21		Algorithm converged.	0,37	3,96	0,7472		0,82		Algorithm converged.	0,25	2,69
		Asia Pacific	482	27,0	8	1,7	517	28,4	7	1,4	1,23		Algorithm converged.	0,44	3,42	0,003		Algorithm converged.	-0,012	0,018		1,23		Algorithm converged.	0,45	3,35	0,6918		0,82		Algorithm converged.	0,30	2,23
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005		0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8	1,07		Algorithm converged.	0,27	4,32	0,001		Algorithm converged.	-0,011	0,012		1,07		Algorithm converged.	0,27	4,26	0,9207		0,93		Algorithm converged.	0,23	3,71
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD ALKALINE PHOSPHATASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD BILIRUBIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk										
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD POTASSIUM DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD PRESSURE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD TRIGLYCERIDES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	C-REACTIVE PROTEIN INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	USA/Canada	262	14,7	8	3,1	252	13,8	4	1,6	1,95		Algorithm converged.	0,58	6,57	0,015		Algorithm converged.	-0,011	0,041		1,92		Algorithm converged.	0,59	6,31	0,2803	-	0,52		Algorithm converged.	0,16	1,70
		Western Europe	814	45,7	13	1,6	824	45,2	20	2,4	0,65		Algorithm converged.	0,32	1,32	-0,008		Algorithm converged.	-0,022	0,005		0,66		Algorithm converged.	0,33	1,31	0,2355		1,52		Algorithm converged.	0,76	3,03
		Asia Pacific	482	27,0	6	1,2	517	28,4	6	1,2	1,07		Algorithm converged.	0,34	3,35	0,001		Algorithm converged.	-0,013	0,014		1,07		Algorithm converged.	0,35	3,30	0,9028		0,93		Algorithm converged.	0,30	2,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	GAMMA-GLUTAMYLTRANSFERASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	2	0,2	824	45,2	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,005		Algorithm converged.	-0,012	0,002	0,34		Algorithm converged.	0,07	1,67	0,1825		2,96		Algorithm converged.	0,60	14,64	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	GLOMERULAR FILTRATION RATE DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	HAEMOGLOBIN DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HEPATIC ENZYME INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIPASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER FUNCTION TEST INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	LYMPHOCYTE COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	3	1,1	252	13,8	5	2,0	0,57		Algorithm converged.	0,14	2,42	-0,008		Algorithm converged.	-0,030	0,013	0,58		Algorithm converged.	0,14	2,39	0,4483	-	1,73		Algorithm converged.	0,42	7,18
		Western Europe	814	45,7	26	3,2	824	45,2	38	4,6	0,68		Algorithm converged.	0,41	1,13	-0,014		Algorithm converged.	-0,033	0,005	0,69		Algorithm converged.	0,42	1,13	0,1413		1,44		Algorithm converged.	0,89	2,36
		Asia Pacific	482	27,0	40	8,3	517	28,4	31	6,0	1,42		Algorithm converged.	0,87	2,31	0,023		Algorithm converged.	-0,009	0,055	1,38		Algorithm converged.	0,88	2,18	0,1590		0,72		Algorithm converged.	0,46	1,14
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	NEUTROPHIL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	5	1,0	517	28,4	2	0,4	2,70		Algorithm converged.	0,52	13,98	0,007		Algorithm converged.	-0,004	0,017	2,68		Algorithm converged.	0,52	13,76	0,2371		0,37		Algorithm converged.	0,07	1,91
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSAMINASES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN T INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINE OUTPUT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WEIGHT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	4	1,5	252	13,8	5	2,0	0,77		Algorithm converged.	0,20	2,89	-0,005		Algorithm converged.	-0,027	0,018	0,77		Algorithm converged.	0,21	2,83	0,6935	-	1,30		Algorithm converged.	0,35	4,78
		Western Europe	814	45,7	24	2,9	824	45,2	20	2,4	1,22		Algorithm converged.	0,67	2,23	0,005		Algorithm converged.	-0,010	0,021	1,21		Algorithm converged.	0,68	2,18	0,5149		0,82		Algorithm converged.	0,46	1,48
		Asia Pacific	482	27,0	46	9,5	517	28,4	25	4,8	2,08		Algorithm converged.	1,25	3,44	0,047		Algorithm converged.	0,015	0,079	1,97		Algorithm converged.	1,23	3,16	0,0047		0,51		Algorithm converged.	0,32	0,81
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	34	13,0	252	13,8	13	5,2	2,74		Algorithm converged.	1,41	5,33	0,078		Algorithm converged.	0,029	0,127	2,52		Algorithm converged.	1,36	4,65	0,0033	-	0,40		Algorithm converged.	0,21	0,74
		Western Europe	814	45,7	20	2,5	824	45,2	11	1,3	1,86		Algorithm converged.	0,89	3,91	0,011		Algorithm converged.	-0,002	0,024	1,84		Algorithm converged.	0,89	3,82	0,1011		0,54		Algorithm converged.	0,26	1,13
		Asia Pacific	482	27,0	24	5,0	517	28,4	14	2,7	1,88		Algorithm converged.	0,96	3,68	0,023		Algorithm converged.	-0,001	0,047	1,84		Algorithm converged.	0,96	3,51	0,0652		0,54		Algorithm converged.	0,28	1,04
		Latin America	42	2,4	3	7,1	45	2,5	2	4,4	1,65		Algorithm converged.	0,26	10,42	0,027		Algorithm converged.	-0,071	0,125	1,61		Algorithm converged.	0,28	9,15	0,5928		0,62		Algorithm converged.	0,11	3,54
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DECREASED APPETITE	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009		4,05		Algorithm converged.	0,45	36,15	0,2105			0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	10	2,1	517	28,4	6	1,2	1,80		Algorithm converged.	0,65	5,00	0,009		Algorithm converged.	-0,007	0,025		1,79		Algorithm converged.	0,65	4,88	0,2570			0,56		Algorithm converged.	0,20	1,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DEHYDRATION	USA/Canada	262	14,7	10	3,8	252	13,8	2	0,8	4,96		Algorithm converged.	1,08	22,87	0,030		Algorithm converged.	0,005	0,056		4,81		Algorithm converged.	1,06	21,73	0,0413	-		0,21		Algorithm converged.	0,05	0,94
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326			0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DIABETES MELLITUS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIABETIC METABOLIC DECOMPENSATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FAILURE TO THRIVE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028		3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	0	0,0	824	45,2	4	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2	4,32		Algorithm converged.	0,48	38,77	0,006		Algorithm converged.	-0,003	0,015		4,29		Algorithm converged.	0,48	38,25	0,1920		0,23		Algorithm converged.	0,03	2,08
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERKALAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERMAGNESAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	USA/Canada	262	14,7	12	4,6	252	13,8	5	2,0	2,37		Algorithm converged.	0,82	6,83	0,026		Algorithm converged.	-0,005	0,057	2,31		Algorithm converged.	0,83	6,46	0,1110	-	0,43		Algorithm converged.	0,15	1,21
		Western Europe	814	45,7	6	0,7	824	45,2	1	0,1	6,11		Algorithm converged.	0,73	50,88	0,006		Algorithm converged.	0,000	0,012	6,07		Algorithm converged.	0,73	50,34	0,0945		0,16		Algorithm converged.	0,02	1,36
		Asia Pacific	482	27,0	8	1,7	517	28,4	4	0,8	2,16		Algorithm converged.	0,65	7,23	0,009		Algorithm converged.	-0,005	0,023	2,15		Algorithm converged.	0,65	7,08	0,2102		0,47		Algorithm converged.	0,14	1,54
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	9	3,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPONATRAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPROTEINAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIPOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TETANY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	TUMOUR LYSIS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	USA/Canada	262	14,7	7	2,7	252	13,8	10	4,0	0,66		Algorithm converged.	0,25	1,77	-0,013		Algorithm converged.	-0,044	0,018		0,67		Algorithm converged.	0,26	1,74	0,4145	-	1,49		Algorithm converged.	0,57	3,84	
		Western Europe	814	45,7	22	2,7	824	45,2	37	4,5	0,59		Algorithm converged.	0,35	1,01	-0,018		Algorithm converged.	-0,036	0,000		0,60		Algorithm converged.	0,36	1,01	0,0551		1,66		Algorithm converged.	0,99	2,79	
		Asia Pacific	482	27,0	1	0,2	517	28,4	5	1,0	0,21		Algorithm converged.	0,02	1,83	-0,008		Algorithm converged.	-0,017	0,002		0,21		Algorithm converged.	0,03	1,83	0,1593		4,66		Algorithm converged.	0,55	39,76	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	ARTHRALGIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	8	1,0	824	45,2	18	2,2	0,44		Algorithm converged.	0,19	1,03	-0,012		Algorithm converged.	-0,024	0,000	0,45		Algorithm converged.	0,20	1,03	0,0584		2,22		Algorithm converged.	0,97	5,08
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACK PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BONE PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002		0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	INTERVERTEBRAL DISC PROTRUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULAR WEAKNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	5	0,6	824	45,2	3	0,4	1,69		Algorithm converged.	0,40	7,10	0,003		Algorithm converged.	-0,004	0,009		1,69		Algorithm converged.	0,40	7,04	0,4729		0,59		Algorithm converged.	0,14	2,47

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	11	1,4	824	45,2	17	2,1	0,65		Algorithm converged.	0,30	1,40	-0,007		Algorithm converged.	-0,020	0,005	0,66		Algorithm converged.	0,31	1,39	0,2703		1,53		Algorithm converged.	0,72	3,24
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN IN EXTREMITY	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017	1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	SJOGREN'S SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL OSTEOARTHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SPINAL STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	4	0,5	1,01		Algorithm converged.	0,25	4,06	0,000		Algorithm converged.	-0,007	0,007		1,01		Algorithm converged.	0,25	4,03	0,9862		0,99		Algorithm converged.	0,25	3,94
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BASAL CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LENTIGO MALIGNA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONOCLONAL GAMMOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PAPILLARY THYROID CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	SQUAMOUS CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	16	6,1	252	13,8	16	6,3	0,96		Algorithm converged.	0,47	1,96	-0,002		Algorithm converged.	-0,044	0,039	0,96		Algorithm converged.	0,49	1,88	0,9095	-	1,04		Algorithm converged.	0,53	2,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	46	5,7	824	45,2	29	3,5	1,64		Algorithm converged.	1,02	2,64	0,021		Algorithm converged.	0,001	0,042	1,61		Algorithm converged.	1,02	2,53	0,0411		0,62		Algorithm converged.	0,40	0,98
		Asia Pacific	482	27,0	6	1,2	517	28,4	8	1,5	0,80		Algorithm converged.	0,28	2,33	-0,003		Algorithm converged.	-0,018	0,012	0,80		Algorithm converged.	0,28	2,30	0,6850		1,24		Algorithm converged.	0,43	3,56
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103	2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BURNING SENSATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARPAL TUNNEL SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL RADICULOPATHY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSGEUSIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEADACHE	USA/Canada	262	14,7	0	0,0	252	13,8	4	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTERCOSTAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LETHARGY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MIGRAINE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUROPATHY PERIPHERAL	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUROTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010	2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERIPHERAL MOTOR NEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	PERIPHERAL SENSORY NEUROPATHY	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	9	1,1	824	45,2	5	0,6	1,83		Algorithm converged.	0,61	5,49	0,005		Algorithm converged.	-0,004	0,014	1,82		Algorithm converged.	0,61	5,41	0,2802		0,55		Algorithm converged.	0,18	1,63
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POLYNEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRESYNCOPE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCIATICA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	USA/Canada	262	14,7	6	2,3	252	13,8	7	2,8	0,82		Algorithm converged.	0,27	2,48	-0,005		Algorithm converged.	-0,032	0,022	0,82		Algorithm converged.	0,28	2,42	0,7252	-	1,21		Algorithm converged.	0,41	3,56
		Western Europe	814	45,7	8	1,0	824	45,2	2	0,2	4,08		Algorithm converged.	0,86	19,27	0,007		Algorithm converged.	0,000	0,015	4,05		Algorithm converged.	0,86	19,01	0,0763		0,25		Algorithm converged.	0,05	1,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	0,069	*	WARNING: The relative Hessian convergence criterion of 5.5320812981 is greater than the limit of 0.0001. The convergence is questionable.	-0,237	0,376		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015		1,01		Algorithm converged.	0,06	15,95	0,9969			0,99		Algorithm converged.	0,06	15,78
	THALAMIC INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PRODUCT ISSUE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE EXTRUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023	1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011	1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANXIETY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EMOTIONAL DISTRESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INSOMNIA	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32	
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MAJOR DEPRESSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MENTAL DISORDER	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PSYCHOTIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010	0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk								Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLADDER PROLAPSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	DYSURIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEPHROLITHIASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036		2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	16	2,0	824	45,2	27	3,3	0,59		Algorithm converged.	0,32	1,11	-0,013		Algorithm converged.	-0,029	0,002		0,60		Algorithm converged.	0,33	1,10	0,1010		1,67		Algorithm converged.	0,91	3,07
		Asia Pacific	482	27,0	6	1,2	517	28,4	7	1,4	0,92		Algorithm converged.	0,31	2,75	-0,001		Algorithm converged.	-0,015	0,013		0,92		Algorithm converged.	0,31	2,72	0,8791		1,09		Algorithm converged.	0,37	3,21
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	1	0,5	4,09		Algorithm converged.	0,45	36,94	0,016		Algorithm converged.	-0,007	0,040		4,02		Algorithm converged.	0,45	35,64	0,2112		0,25		Algorithm converged.	0,03	2,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMENORRHOEA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST HAEMATOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAVY MENSTRUAL BLEEDING	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUATION IRREGULAR	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4	3,89		Algorithm converged.	0,43	35,06	0,011		Algorithm converged.	-0,005	0,028	3,85		Algorithm converged.	0,43	34,19	0,2267	-	0,26		Algorithm converged.	0,03	2,31
		Western Europe	814	45,7	9	1,1	824	45,2	15	1,8	0,60		Algorithm converged.	0,26	1,39	-0,007		Algorithm converged.	-0,019	0,004	0,61		Algorithm converged.	0,27	1,38	0,2337		1,65		Algorithm converged.	0,72	3,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	4	0,8	517	28,4	6	1,2	0,71		Algorithm converged.	0,20	2,54	-0,003		Algorithm converged.	-0,016	0,009	0,72		Algorithm converged.	0,20	2,52	0,6016		1,40		Algorithm converged.	0,40	4,93
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PREMATURE MENOPAUSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL DRYNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	6	2,4	0,96		Algorithm converged.	0,31	3,02	-0,001		Algorithm converged.	-0,027	0,025		0,96		Algorithm converged.	0,31	2,94	0,9456	-	1,04		Algorithm converged.	0,34	3,18
		Western Europe	814	45,7	15	1,8	824	45,2	14	1,7	1,09		Algorithm converged.	0,52	2,26	0,001		Algorithm converged.	-0,011	0,014		1,08		Algorithm converged.	0,53	2,23	0,8255		0,92		Algorithm converged.	0,45	1,90
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065		1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE RESPIRATORY DISTRESS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASTHMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATARRH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COUGH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	USA/Canada	262	14,7	2	0,8	252	13,8	3	1,2	0,64		Algorithm converged.	0,11	3,85	-0,004		Algorithm converged.	-0,021	0,013	0,64		Algorithm converged.	0,11	3,81	0,6248	-	1,56		Algorithm converged.	0,26	9,26
		Western Europe	814	45,7	4	0,5	824	45,2	7	0,8	0,58		Algorithm converged.	0,17	1,98	-0,004		Algorithm converged.	-0,011	0,004	0,58		Algorithm converged.	0,17	1,97	0,3810		1,73		Algorithm converged.	0,51	5,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EPISTAXIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE	NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL EFFUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONITIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RHINORRHOEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHEEZING	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	7	2,7	252	13,8	5	2,0	1,36		Algorithm converged.	0,42	4,33	0,007		Algorithm converged.	-0,019	0,033	1,35		Algorithm converged.	0,43	4,19	0,6072	-	0,74		Algorithm converged.	0,24	2,31
		Western Europe	814	45,7	42	5,2	824	45,2	25	3,0	1,74		Algorithm converged.	1,05	2,88	0,021		Algorithm converged.	0,002	0,040	1,70		Algorithm converged.	1,05	2,76	0,0321		0,59		Algorithm converged.	0,36	0,96
		Asia Pacific	482	27,0	11	2,3	517	28,4	3	0,6	4,00		Algorithm converged.	1,11	14,43	0,017		Algorithm converged.	0,002	0,032	3,93		Algorithm converged.	1,10	14,01	0,0347		0,25		Algorithm converged.	0,07	0,91
		Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055	0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALOPECIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGIOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLISTER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ACNEIFORM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG ERUPTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
	ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003	0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
	EXFOLIATIVE RASH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL DISCOLOURATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NAIL TOXICITY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NIGHT SWEATS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOCLASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ONYCHOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ONYCHOMADESIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4	2,91		Algorithm converged.	0,30	28,14	0,007		Algorithm converged.	-0,008	0,023	2,89		Algorithm converged.	0,30	27,56	0,3574	-	0,35		Algorithm converged.	0,04	3,31
		Western Europe	814	45,7	12	1,5	824	45,2	4	0,5	3,07		Algorithm converged.	0,99	9,55	0,010		Algorithm converged.	0,000	0,019	3,04		Algorithm converged.	0,98	9,38	0,0535		0,33		Algorithm converged.	0,11	1,02
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHOTOSENSITIVITY REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSORIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	7	0,9	824	45,2	4	0,5	1,78		Algorithm converged.	0,52	6,10	0,004		Algorithm converged.	-0,004	0,012	1,77		Algorithm converged.	0,52	6,03	0,3601		0,56		Algorithm converged.	0,17	1,92
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULAR	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH MACULO-PAPULAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SCAR PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN IRRITATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SKIN REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SKIN TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945854 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC SKIN ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	URTICARIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST RECONSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	9	3,4	252	13,8	8	3,2	1,08		Algorithm converged.	0,41	2,86	0,003		Algorithm converged.	-0,028	0,034		1,08		Algorithm converged.	0,42	2,76	0,8689	-	0,92		Algorithm converged.	0,36	2,36
		Western Europe	814	45,7	23	2,8	824	45,2	31	3,8	0,74		Algorithm converged.	0,43	1,29	-0,009		Algorithm converged.	-0,027	0,008		0,75		Algorithm converged.	0,44	1,28	0,2903		1,33		Algorithm converged.	0,78	2,26
		Asia Pacific	482	27,0	4	0,8	517	28,4	7	1,4	0,61		Algorithm converged.	0,18	2,10	-0,005		Algorithm converged.	-0,018	0,008		0,61		Algorithm converged.	0,18	2,08	0,4324		1,63		Algorithm converged.	0,48	5,54
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.073145902 3 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	3	1,6	184	10,1	6	3,3	0,49		Algorithm converged.	0,12	2,01	-0,016		Algorithm converged.	-0,048	0,015	0,50		Algorithm converged.	0,13	1,98	0,3254		1,99		Algorithm converged.	0,51	7,83
	AXILLARY VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMBOLISM	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HOT FLUSH	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004		0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	USA/Canada	262	14,7	4	1,5	252	13,8	5	2,0	0,77		Algorithm converged.	0,20	2,89	-0,005		Algorithm converged.	-0,027	0,018		0,77		Algorithm converged.	0,21	2,83	0,6935	-	1,30		Algorithm converged.	0,35	4,78
		Western Europe	814	45,7	13	1,6	824	45,2	16	1,9	0,82		Algorithm converged.	0,39	1,71	-0,003		Algorithm converged.	-0,016	0,009		0,82		Algorithm converged.	0,40	1,70	0,5975		1,22		Algorithm converged.	0,59	2,51
		Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013		1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4	0,00		Algorithm converged.	0,00	NE	-0,066	*	WARNING: The relative Hessian convergence criterion of 5.0731459023 is greater than the limit of 0.0001. The convergence is questionable.	-0,381	0,248		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	6	3,3	0,33		Algorithm converged.	0,07	1,65	-0,022		Algorithm converged.	-0,051	0,008		0,34		Algorithm converged.	0,07	1,64	0,1770		2,98		Algorithm converged.	0,61	14,59
	HYPOTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004		0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	JUGULAR VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORTHOSTATIC HYPOTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCLAVIAN VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	SUPERIOR VENA CAVA OCCLUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOPHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENOUS THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR3_S1.xls
05MAY2022 17:21

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	14	27,5	42	2,3	9	21,4	1,39		Algorithm converged.	0,53	3,62	0,060		Algorithm converged.	-0,114	0,235		1,28		Algorithm converged.	0,62	2,66	0,5067	0,3749	0,78		Algorithm converged.	0,38	1,62
		0 positive nodes, tumor > 1 cm	259	14,5	60	23,2	271	14,9	44	16,2	1,56		Algorithm converged.	1,01	2,40	0,069		Algorithm converged.	0,002	0,137		1,43		Algorithm converged.	1,01	2,02	0,0464		0,70		Algorithm converged.	0,49	0,99
		1-3 positive nodes	891	50,0	211	23,7	905	49,7	210	23,2	1,03		Algorithm converged.	0,83	1,28	0,005		Algorithm converged.	-0,034	0,044		1,02		Algorithm converged.	0,86	1,21	0,8115		0,98		Algorithm converged.	0,83	1,16
		>= 4 positive nodes	582	32,6	134	23,0	604	33,2	125	20,7	1,15		Algorithm converged.	0,87	1,51	0,023		Algorithm converged.	-0,024	0,070		1,11		Algorithm converged.	0,90	1,38	0,3321		0,90		Algorithm converged.	0,72	1,12
	AGRANULOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	3	7,1	1,73		Algorithm converged.	0,41	7,39	0,046		Algorithm converged.	-0,072	0,164		1,65		Algorithm converged.	0,44	6,19	0,4602	-	0,61		Algorithm converged.	0,16	2,28
		0 positive nodes, tumor > 1 cm	259	14,5	18	6,9	271	14,9	16	5,9	1,19		Algorithm converged.	0,59	2,39	0,010		Algorithm converged.	-0,031	0,052		1,18		Algorithm converged.	0,61	2,26	0,6237		0,85		Algorithm converged.	0,44	1,63
		1-3 positive nodes	891	50,0	50	5,6	905	49,7	39	4,3	1,32		Algorithm converged.	0,86	2,03	0,013		Algorithm converged.	-0,007	0,033		1,30		Algorithm converged.	0,87	1,96	0,2051		0,77		Algorithm converged.	0,51	1,16
		>= 4 positive nodes	582	32,6	45	7,7	604	33,2	28	4,6	1,72		Algorithm converged.	1,06	2,80	0,031		Algorithm converged.	0,004	0,058		1,67		Algorithm converged.	1,06	2,64	0,0285		0,60		Algorithm converged.	0,38	0,95
	BONE MARROW FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,7095	0,81		Algorithm converged.	0,24	2,68
		0 positive nodes, tumor > 1 cm	259	14,5	21	8,1	271	14,9	14	5,2	1,62		Algorithm converged.	0,81	3,26	0,029		Algorithm converged.	-0,013	0,072	1,57		Algorithm converged.	0,82	3,02	0,1770		0,64		Algorithm converged.	0,33	1,23
		1-3 positive nodes	891	50,0	77	8,6	905	49,7	76	8,4	1,03		Algorithm converged.	0,74	1,44	0,002		Algorithm converged.	-0,023	0,028	1,03		Algorithm converged.	0,76	1,39	0,8530		0,97		Algorithm converged.	0,72	1,32
		>= 4 positive nodes	582	32,6	48	8,2	604	33,2	46	7,6	1,09		Algorithm converged.	0,72	1,66	0,006		Algorithm converged.	-0,024	0,037	1,08		Algorithm converged.	0,73	1,60	0,6874		0,92		Algorithm converged.	0,63	1,36
	GRANULOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	HAEMATOTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	IRON DEFICIENCY ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LEUKOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	1	2,4	2,56		Algorithm converged.	0,26	25,59	0,035		Algorithm converged.	-0,044	0,114	2,47		Algorithm converged.	0,27	22,88	0,4258	-	0,40		Algorithm converged.	0,04	3,75
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	6	2,2	0,87		Algorithm converged.	0,26	2,88	-0,003		Algorithm converged.	-0,027	0,021	0,87		Algorithm converged.	0,27	2,82	0,8191		1,15		Algorithm converged.	0,35	3,71
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	29	3,2	1,16		Algorithm converged.	0,70	1,93	0,005		Algorithm converged.	-0,012	0,022	1,16		Algorithm converged.	0,71	1,89	0,5626		0,87		Algorithm converged.	0,53	1,41

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	29	4,8	0,67		Algorithm converged.	0,37	1,21	-0,015		Algorithm converged.	-0,038	0,007	0,68		Algorithm converged.	0,39	1,20	0,1825		1,47		Algorithm converged.	0,83	2,59
	LYMPHOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	2	4,8	1,70		Algorithm converged.	0,30	9,78	0,031		Algorithm converged.	-0,067	0,129		1,65		Algorithm converged.	0,32	8,55	0,5528	-	0,61		Algorithm converged.	0,12	3,15
		0 positive nodes, tumor > 1 cm	259	14,5	19	7,3	271	14,9	11	4,1	1,87		Algorithm converged.	0,87	4,01	0,033		Algorithm converged.	-0,007	0,072		1,81		Algorithm converged.	0,88	3,72	0,1085		0,55		Algorithm converged.	0,27	1,14
		1-3 positive nodes	891	50,0	71	8,0	905	49,7	83	9,2	0,86		Algorithm converged.	0,62	1,19	-0,012		Algorithm converged.	-0,038	0,014		0,87		Algorithm converged.	0,64	1,18	0,3633		1,15		Algorithm converged.	0,85	1,56
		>= 4 positive nodes	582	32,6	35	6,0	604	33,2	37	6,1	0,98		Algorithm converged.	0,61	1,58	-0,001		Algorithm converged.	-0,028	0,026		0,98		Algorithm converged.	0,63	1,54	0,9356		1,02		Algorithm converged.	0,65	1,59
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	3	1,1	0,70		Algorithm converged.	0,12	4,19	-0,003		Algorithm converged.	-0,020	0,013		0,70		Algorithm converged.	0,12	4,14	0,6918		1,43		Algorithm converged.	0,24	8,51
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	6	0,7	1,36		Algorithm converged.	0,47	3,93	0,002		Algorithm converged.	-0,006	0,010		1,35		Algorithm converged.	0,47	3,89	0,5730		0,74		Algorithm converged.	0,26	2,12
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	6	1,0	0,34		Algorithm converged.	0,07	1,71	-0,006		Algorithm converged.	-0,016	0,003		0,35		Algorithm converged.	0,07	1,71	0,1924		2,89		Algorithm converged.	0,59	14,26

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	13	1,4	0,47		Algorithm converged.	0,18	1,23	-0,008		Algorithm converged.	-0,017	0,002	0,47		Algorithm converged.	0,18	1,23	0,1231		2,13		Algorithm converged.	0,81	5,59
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	6	1,0	2,28		Algorithm converged.	0,86	6,03	0,012		Algorithm converged.	-0,002	0,027	2,25		Algorithm converged.	0,86	5,88	0,0983		0,44		Algorithm converged.	0,17	1,16
	ACUTE CORONARY SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	ATRIAL FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801536 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATRIAL THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	5	0,6	0,81		Algorithm converged.	0,22	3,03	-0,001		Algorithm converged.	-0,008	0,005		0,81		Algorithm converged.	0,22	3,02	0,7564		1,23		Algorithm converged.	0,33	4,57
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	1	0,2	5,23		Algorithm converged.	0,61	44,86	0,007		Algorithm converged.	-0,001	0,015		5,19		Algorithm converged.	0,61	44,28	0,1323		0,19		Algorithm converged.	0,02	1,64
	CARDIAC FAILURE CONGESTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CORONARY ARTERY STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERTENSIVE CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MITRAL VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUPRAVENTRICULAR TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	TACHYCARDIA PAROXYSMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRICUSPID VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENTRICULAR ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXTERNAL EAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOACUSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VERTIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GOITRE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE			
EYE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE			
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CATARACT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRY EYE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LACRIMATION INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RETINAL DETACHMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RETINAL VASCULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VITREOUS FLOATERS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	10	19,6	42	2,3	7	16,7	1,22		Algorithm converged.	0,42	3,54	0,029		Algorithm converged.	-0,127	0,186	1,18		Algorithm converged.	0,49	2,82	0,7159	0,7741	0,85		Algorithm converged.	0,35	2,04
		0 positive nodes, tumor > 1 cm	259	14,5	42	16,2	271	14,9	25	9,2	1,90		Algorithm converged.	1,12	3,23	0,070		Algorithm converged.	0,013	0,126	1,76		Algorithm converged.	1,10	2,80	0,0174		0,57		Algorithm converged.	0,36	0,91
		1-3 positive nodes	891	50,0	137	15,4	905	49,7	89	9,8	1,67		Algorithm converged.	1,25	2,21	0,055		Algorithm converged.	0,025	0,086	1,56		Algorithm converged.	1,22	2,01	0,0005		0,64		Algorithm converged.	0,50	0,82
		>= 4 positive nodes	582	32,6	74	12,7	604	33,2	42	7,0	1,95		Algorithm converged.	1,31	2,90	0,058		Algorithm converged.	0,024	0,091	1,83		Algorithm converged.	1,27	2,62	0,0011		0,55		Algorithm converged.	0,38	0,78
	ABDOMINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	5	0,6	1,22		Algorithm converged.	0,37	4,01	0,001		Algorithm converged.	-0,006	0,008	1,22		Algorithm converged.	0,37	3,98	0,7430		0,82		Algorithm converged.	0,25	2,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	ABDOMINAL PAIN UPPER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37						
	ANAL FISSURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	ANAL FISTULA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	APHTHOUS ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	COLITIS ISCHAEMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83
	DENTAL CARIES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE		NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE		NE	NE
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082	0,66		Algorithm converged.	0,19	2,30	0,5128	-	1,52		Algorithm converged.	0,43	5,30
		0 positive nodes, tumor > 1 cm	259	14,5	25	9,7	271	14,9	15	5,5	1,82		Algorithm converged.	0,94	3,54	0,041		Algorithm converged.	-0,004	0,086	1,74		Algorithm converged.	0,94	3,23	0,0773		0,57		Algorithm converged.	0,31	1,06
		1-3 positive nodes	891	50,0	87	9,8	905	49,7	35	3,9	2,69		Algorithm converged.	1,80	4,03	0,059		Algorithm converged.	0,036	0,082	2,52		Algorithm converged.	1,72	3,70	<.0001		0,40		Algorithm converged.	0,27	0,58
		>= 4 positive nodes	582	32,6	49	8,4	604	33,2	16	2,6	3,38		Algorithm converged.	1,90	6,01	0,058		Algorithm converged.	0,032	0,084	3,18		Algorithm converged.	1,83	5,52	<.0001		0,31		Algorithm converged.	0,18	0,55
	DRY MOUTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DUODENAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744			0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GLOSSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHOIDS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOOSE TOOTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MOUTH ULCERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 43.712374359 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,068	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAUSEA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	6	2,2	0,69		Algorithm converged.	0,19	2,48	-0,007		Algorithm converged.	-0,030	0,016	0,70		Algorithm converged.	0,20	2,44	0,5734		1,43		Algorithm converged.	0,41	5,02
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	27	3,0	0,75		Algorithm converged.	0,42	1,34	-0,007		Algorithm converged.	-0,022	0,007	0,75		Algorithm converged.	0,43	1,33	0,3286		1,33		Algorithm converged.	0,75	2,35
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	9	1,5	1,16		Algorithm converged.	0,47	2,87	0,002		Algorithm converged.	-0,012	0,017	1,15		Algorithm converged.	0,47	2,82	0,7546		0,87		Algorithm converged.	0,35	2,12
	ORAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STOMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	4	1,5	1,31		Algorithm converged.	0,35	4,95	0,005		Algorithm converged.	-0,018	0,027	1,31		Algorithm converged.	0,36	4,82	0,6865		0,76		Algorithm converged.	0,21	2,82
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	9	1,0	2,29		Algorithm converged.	1,04	5,05	0,013		Algorithm converged.	0,001	0,024	2,26		Algorithm converged.	1,03	4,93	0,0411		0,44		Algorithm converged.	0,20	0,97
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	5	0,8	2,52		Algorithm converged.	0,88	7,20	0,012		Algorithm converged.	-0,001	0,026	2,49		Algorithm converged.	0,88	7,03	0,0846		0,40		Algorithm converged.	0,14	1,13
	SUBILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TOOTH DEVELOPMENT DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VOMITING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	6	2,2	0,34		Algorithm converged.	0,07	1,72	-0,014		Algorithm converged.	-0,035	0,006	0,35		Algorithm converged.	0,07	1,71	0,1945		2,87		Algorithm converged.	0,58	14,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	16	1,8	905	49,7	15	1,7	1,08		Algorithm converged.	0,53	2,21	0,001		Algorithm converged.	-0,011	0,013	1,08		Algorithm converged.	0,54	2,18	0,8221		0,92		Algorithm converged.	0,46	1,86
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	11	1,8	1,13		Algorithm converged.	0,50	2,59	0,002		Algorithm converged.	-0,013	0,018	1,13		Algorithm converged.	0,50	2,55	0,7640		0,88		Algorithm converged.	0,39	1,99
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	2	4,8	2,67		Algorithm converged.	0,51	13,97	0,070		Algorithm converged.	-0,039	0,179	2,47		Algorithm converged.	0,53	11,61	0,2519	-	0,40		Algorithm converged.	0,09	1,90
		0 positive nodes, tumor > 1 cm	259	14,5	15	5,8	271	14,9	15	5,5	1,05		Algorithm converged.	0,50	2,19	0,003		Algorithm converged.	-0,037	0,042	1,05		Algorithm converged.	0,52	2,10	0,8984		0,96		Algorithm converged.	0,48	1,92
		1-3 positive nodes	891	50,0	65	7,3	905	49,7	66	7,3	1,00		Algorithm converged.	0,70	1,43	0,000		Algorithm converged.	-0,024	0,024	1,00		Algorithm converged.	0,72	1,39	0,9985		1,00		Algorithm converged.	0,72	1,39
		>= 4 positive nodes	582	32,6	39	6,7	604	33,2	39	6,5	1,04		Algorithm converged.	0,66	1,65	0,002		Algorithm converged.	-0,026	0,031	1,04		Algorithm converged.	0,68	1,59	0,8654		0,96		Algorithm converged.	0,63	1,48
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	3	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	18	2,0	0,84		Algorithm converged.	0,42	1,68	-0,003		Algorithm converged.	-0,015	0,009	0,85		Algorithm converged.	0,43	1,67	0,6303		1,18		Algorithm converged.	0,60	2,33
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	12	2,0	0,51		Algorithm converged.	0,19	1,38	-0,010		Algorithm converged.	-0,023	0,004	0,52		Algorithm converged.	0,20	1,37	0,1865		1,93		Algorithm converged.	0,73	5,10
	AXILLARY PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004		1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHILLS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FACE OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FACIAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	1	2,4	3,49		Algorithm converged.	0,37	32,48	0,055		Algorithm converged.	-0,032	0,142	3,29		Algorithm converged.	0,38	28,36	0,2778	-	0,30		Algorithm converged.	0,04	2,61
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	7	2,6	1,51		Algorithm converged.	0,57	4,04	0,013		Algorithm converged.	-0,017	0,043	1,49		Algorithm converged.	0,58	3,87	0,4073		0,67		Algorithm converged.	0,26	1,73
		1-3 positive nodes	891	50,0	36	4,0	905	49,7	26	2,9	1,42		Algorithm converged.	0,85	2,38	0,012		Algorithm converged.	-0,005	0,029	1,41		Algorithm converged.	0,86	2,31	0,1777		0,71		Algorithm converged.	0,43	1,17
		>= 4 positive nodes	582	32,6	19	3,3	604	33,2	15	2,5	1,33		Algorithm converged.	0,67	2,63	0,008		Algorithm converged.	-0,011	0,027	1,31		Algorithm converged.	0,67	2,56	0,4218		0,76		Algorithm converged.	0,39	1,48
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	GENERALISED OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFLUENZA LIKE ILLNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INFUSION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INJECTION SITE EXTRAVASATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
	MUCOSAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12	
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	7	0,8	1,60		Algorithm converged.	0,62	4,16	0,005		Algorithm converged.	-0,005	0,014	1,60		Algorithm converged.	0,62	4,10	0,3312		0,63		Algorithm converged.	0,24	1,61	
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	4	0,7	2,09		Algorithm converged.	0,63	6,98	0,007		Algorithm converged.	-0,004	0,019	2,08		Algorithm converged.	0,63	6,86	0,2310		0,48		Algorithm converged.	0,15	1,59	
	OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.62579653 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	PYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	8	0,9	0,38		Algorithm converged.	0,10	1,43	-0,005		Algorithm converged.	-0,013	0,002	0,38		Algorithm converged.	0,10	1,43	0,1529		2,63		Algorithm converged.	0,70	9,86
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	CHOLANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC CYTOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATIC FUNCTION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRANSAMINASAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	10	1,1	0,40		Algorithm converged.	0,13	1,29	-0,007		Algorithm converged.	-0,015	0,002	0,41		Algorithm converged.	0,13	1,29	0,1267		2,46		Algorithm converged.	0,77	7,82
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	ANAPHYLACTIC REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	5	11,9	0,30		Algorithm converged.	0,06	1,64	-0,080		Algorithm converged.	-0,191	0,032	0,33		Algorithm converged.	0,07	1,61	0,1706	-	3,04		Algorithm converged.	0,62	14,86
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	18	6,6	0,56		Algorithm converged.	0,26	1,25	-0,028		Algorithm converged.	-0,066	0,010	0,58		Algorithm converged.	0,27	1,24	0,1585		1,72		Algorithm converged.	0,81	3,66
		1-3 positive nodes	891	50,0	64	7,2	905	49,7	43	4,8	1,55		Algorithm converged.	1,04	2,31	0,024		Algorithm converged.	0,002	0,046	1,51		Algorithm converged.	1,04	2,20	0,0309		0,66		Algorithm converged.	0,45	0,96
		>= 4 positive nodes	582	32,6	41	7,0	604	33,2	41	6,8	1,04		Algorithm converged.	0,66	1,63	0,003		Algorithm converged.	-0,026	0,031	1,04		Algorithm converged.	0,68	1,58	0,8618		0,96		Algorithm converged.	0,63	1,46
	ABDOMINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS LIMB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APPENDICITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	BREAST ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREAST CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	BRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	CATHETER SITE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	6	1,0	0,86		Algorithm converged.	0,26	2,85	-0,001		Algorithm converged.	-0,012	0,010	0,86		Algorithm converged.	0,27	2,82	0,8096		1,16		Algorithm converged.	0,35	3,77
	CLOSTRIDIUM COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	CLOSTRIDIUM DIFFICILE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CYSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEVICE RELATED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996293 9 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
	DIARRHOEA INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DISSEMINATED TUBERCULOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	ENDOCARDITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ERYSIPELAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EYE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FURUNCLE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009		2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	GINGIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GROIN ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	H1N1 INFLUENZA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATITIS B REACTIVATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES OPHTHALMIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HERPES SIMPLEX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES VIRUS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HERPES ZOSTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOCALISED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	LYMPHANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MASTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689			1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	MUCOSAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	NAIL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE		NE			Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL FUNGAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OROPHARYNGITIS FUNGAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC INFLAMMATORY DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
	PERITONSILLAR ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHARYNGITIS BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PHLEBITIS INFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959			1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	5	0,6	0,81		Algorithm converged.	0,22	3,03	-0,001		Algorithm converged.	-0,008	0,005		0,81		Algorithm converged.	0,22	3,02	0,7564			1,23		Algorithm converged.	0,33	4,57
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008		1,04		Algorithm converged.	0,21	5,12	0,9637			0,96		Algorithm converged.	0,20	4,75
	PNEUMONIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE					
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					
	PNEUMONIA PNEUMOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE					
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	POSTOPERATIVE WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PSEUDOMONAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	PYELONEPHRITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RENAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821886 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112		NE		Algorithm converged.	NE	NE	NE				Algorithm converged.	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-				NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999				Algorithm converged.	0,00	NE		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809				Algorithm converged.	0,48	12,65		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791				Algorithm converged.	0,06	15,37		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SOFT TISSUE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCUTANEOUS ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOOTH ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOOTH INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007	0,35		Algorithm converged.	0,04	3,33	0,3603		2,87		Algorithm converged.	0,30	27,39

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006		0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	URINARY TRACT INFECTION ENTEROCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY TRACT INFECTION PSEUDOMONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	VASCULAR DEVICE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVOVAGINAL CANDIDIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	WOUND INFECTION STAPHYLOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	3	1,1	1,05		Algorithm converged.	0,21	5,23	0,001		Algorithm converged.	-0,018	0,019	1,05		Algorithm converged.	0,21	5,14	0,9555		0,96		Algorithm converged.	0,19	4,69
		1-3 positive nodes	891	50,0	19	2,1	905	49,7	12	1,3	1,62		Algorithm converged.	0,78	3,36	0,008		Algorithm converged.	-0,004	0,020	1,61		Algorithm converged.	0,79	3,29	0,1939		0,62		Algorithm converged.	0,30	1,27
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	14	2,3	0,51		Algorithm converged.	0,21	1,28	-0,011		Algorithm converged.	-0,026	0,004	0,52		Algorithm converged.	0,21	1,28	0,1531		1,93		Algorithm converged.	0,78	4,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	ACCIDENTAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FALL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEMORAL NECK FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	FOOT FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	GRAFT THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HAND FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ILIUM FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INCISION SITE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTENTIONAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIGAMENT SPRAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LOWER LIMB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIATION INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIATION SKIN INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RADIUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECALL PHENOMENON	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THERMAL BURN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TIBIA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ULNA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR ACCESS COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	2	4,8	3,72		Algorithm converged.	0,75	18,58	0,109		Algorithm converged.	-0,010	0,228	3,29		Algorithm converged.	0,74	14,69	0,1180	0,3821	0,30		Algorithm converged.	0,07	1,35
		0 positive nodes, tumor > 1 cm	259	14,5	27	10,4	271	14,9	23	8,5	1,25		Algorithm converged.	0,70	2,25	0,019		Algorithm converged.	-0,030	0,069	1,23		Algorithm converged.	0,72	2,09	0,4465		0,81		Algorithm converged.	0,48	1,38
		1-3 positive nodes	891	50,0	102	11,4	905	49,7	100	11,0	1,04		Algorithm converged.	0,78	1,39	0,004		Algorithm converged.	-0,025	0,033	1,04		Algorithm converged.	0,80	1,34	0,7895		0,97		Algorithm converged.	0,74	1,25
		>= 4 positive nodes	582	32,6	71	12,2	604	33,2	71	11,8	1,04		Algorithm converged.	0,73	1,48	0,004		Algorithm converged.	-0,033	0,041	1,04		Algorithm converged.	0,76	1,41	0,8137		0,96		Algorithm converged.	0,71	1,31
	ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ALANINE AMINOTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	8	0,9	0,89		Algorithm converged.	0,32	2,46	-0,001		Algorithm converged.	-0,009	0,007		0,89		Algorithm converged.	0,32	2,44	0,8190		1,13		Algorithm converged.	0,41	3,09
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	5	0,8	1,46		Algorithm converged.	0,46	4,62	0,004		Algorithm converged.	-0,008	0,015		1,45		Algorithm converged.	0,46	4,55	0,5214		0,69		Algorithm converged.	0,22	2,16
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	3	0,3	1,36		Algorithm converged.	0,30	6,08	0,001		Algorithm converged.	-0,005	0,007	1,35		Algorithm converged.	0,30	6,03	0,6908		0,74		Algorithm converged.	0,17	3,29
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
	BLOOD ALKALINE PHOSPHATASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD BILIRUBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD LACTATE DEHYDROGENASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLOOD MAGNESIUM INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131306 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BLOOD POTASSIUM DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD PRESSURE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD TRIGLYCERIDES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	C-REACTIVE PROTEIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	2	0,7	2,11		Algorithm converged.	0,38	11,62	0,008		Algorithm converged.	-0,010	0,026	2,09		Algorithm converged.	0,39	11,33	0,3914		0,48		Algorithm converged.	0,09	2,59
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	14	1,5	1,02		Algorithm converged.	0,48	2,14	0,000		Algorithm converged.	-0,011	0,012	1,02		Algorithm converged.	0,49	2,12	0,9668		0,98		Algorithm converged.	0,47	2,05
		>= 4 positive nodes	582	32,6	10	1,7	604	33,2	14	2,3	0,74		Algorithm converged.	0,32	1,67	-0,006		Algorithm converged.	-0,022	0,010	0,74		Algorithm converged.	0,33	1,66	0,4652		1,35		Algorithm converged.	0,60	3,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	5	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9998		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	GLOMERULAR FILTRATION RATE DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	HEPATIC ENZYME INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LIPASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	LIVER FUNCTION TEST INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOCYTE COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	8	3,0	1,05		Algorithm converged.	0,39	2,83	0,001		Algorithm converged.	-0,028	0,031	1,05		Algorithm converged.	0,40	2,75	0,9267		0,96		Algorithm converged.	0,36	2,51
		1-3 positive nodes	891	50,0	35	3,9	905	49,7	37	4,1	0,96		Algorithm converged.	0,60	1,54	-0,002		Algorithm converged.	-0,020	0,017	0,96		Algorithm converged.	0,61	1,51	0,8626		1,04		Algorithm converged.	0,66	1,64
		>= 4 positive nodes	582	32,6	25	4,3	604	33,2	30	5,0	0,86		Algorithm converged.	0,50	1,48	-0,007		Algorithm converged.	-0,031	0,017	0,86		Algorithm converged.	0,51	1,45	0,5830		1,16		Algorithm converged.	0,69	1,94
	NEUTROPHIL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PLATELET COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	1	0,1	12,34		Algorithm converged.	1,60	95,11	0,012		Algorithm converged.	0,004	0,020	12,19		Algorithm converged.	1,59	93,54	0,0162		0,08		Algorithm converged.	0,01	0,63
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
	TRANSAMINASES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TROPONIN T INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINE OUTPUT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WEIGHT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WEIGHT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	1	2,4	4,46		Algorithm converged.	0,50	39,74	0,074		Algorithm converged.	-0,020	0,168	4,12		Algorithm converged.	0,50	33,89	0,1882	-	0,24		Algorithm converged.	0,03	2,00
		0 positive nodes, tumor > 1 cm	259	14,5	12	4,6	271	14,9	9	3,3	1,41		Algorithm converged.	0,59	3,42	0,013		Algorithm converged.	-0,020	0,046	1,40		Algorithm converged.	0,60	3,26	0,4412		0,72		Algorithm converged.	0,31	1,67
		1-3 positive nodes	891	50,0	33	3,7	905	49,7	27	3,0	1,25		Algorithm converged.	0,75	2,10	0,007		Algorithm converged.	-0,009	0,024	1,24		Algorithm converged.	0,75	2,05	0,3967		0,81		Algorithm converged.	0,49	1,33
		>= 4 positive nodes	582	32,6	26	4,5	604	33,2	15	2,5	1,84		Algorithm converged.	0,96	3,50	0,020		Algorithm converged.	-0,001	0,041	1,80		Algorithm converged.	0,96	3,36	0,0657		0,56		Algorithm converged.	0,30	1,04
	WHITE BLOOD CELL COUNT INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	4	9,5	0,39		Algorithm converged.	0,07	2,23	-0,056		Algorithm converged.	-0,160	0,048		0,41		Algorithm converged.	0,08	2,14	0,2912	-	2,43		Algorithm converged.	0,47	12,61
		0 positive nodes, tumor > 1 cm	259	14,5	11	4,2	271	14,9	8	3,0	1,46		Algorithm converged.	0,58	3,69	0,013		Algorithm converged.	-0,019	0,045		1,44		Algorithm converged.	0,59	3,52	0,4255		0,70		Algorithm converged.	0,28	1,70
		1-3 positive nodes	891	50,0	41	4,6	905	49,7	18	2,0	2,38		Algorithm converged.	1,35	4,17	0,026		Algorithm converged.	0,010	0,043		2,31		Algorithm converged.	1,34	4,00	0,0026		0,43		Algorithm converged.	0,25	0,75
		>= 4 positive nodes	582	32,6	29	5,0	604	33,2	10	1,7	3,12		Algorithm converged.	1,50	6,45	0,033		Algorithm converged.	0,013	0,054		3,01		Algorithm converged.	1,48	6,12	0,0023		0,33		Algorithm converged.	0,16	0,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	2	0,3	2,61		Algorithm converged.	0,50	13,50	0,005		Algorithm converged.	-0,004	0,014	2,59		Algorithm converged.	0,51	13,32	0,2533		0,39		Algorithm converged.	0,08	1,98
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	1	0,1	10,26		Algorithm converged.	1,31	80,32	0,010		Algorithm converged.	0,003	0,017	10,16		Algorithm converged.	1,30	79,18	0,0269		0,10		Algorithm converged.	0,01	0,77
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIABETES MELLITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIABETIC METABOLIC DECOMPENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FAILURE TO THRIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013	1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTRIGLYCERIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	7	0,8	2,20		Algorithm converged.	0,89	5,41	0,009		Algorithm converged.	-0,001	0,019	2,18		Algorithm converged.	0,89	5,31	0,0876		0,46		Algorithm converged.	0,19	1,12
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	3	0,5	3,15		Algorithm converged.	0,85	11,68	0,010		Algorithm converged.	-0,001	0,022	3,11		Algorithm converged.	0,85	11,44	0,0873		0,32		Algorithm converged.	0,09	1,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	1	0,1	7,16		Algorithm converged.	0,88	58,30	0,007		Algorithm converged.	0,001	0,013		7,11		Algorithm converged.	0,88	57,67	0,0663		0,14		Algorithm converged.	0,02	1,14	
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	HYPONATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006		1,52		Algorithm converged.	0,26	9,10	0,6442			0,66		Algorithm converged.	0,11	3,92
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPROTEINAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LIPOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TETANY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TUMOUR LYSIS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	10	3,7	0,41		Algorithm converged.	0,13	1,32	-0,021		Algorithm converged.	-0,048	0,006		0,42		Algorithm converged.	0,13	1,32	0,1366		2,39		Algorithm converged.	0,76	7,52
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	29	3,2	0,69		Algorithm converged.	0,39	1,24	-0,010		Algorithm converged.	-0,025	0,005		0,70		Algorithm converged.	0,40	1,23	0,2145		1,43		Algorithm converged.	0,81	2,50
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	15	2,5	0,62		Algorithm converged.	0,27	1,42	-0,009		Algorithm converged.	-0,025	0,007		0,62		Algorithm converged.	0,27	1,41	0,2566		1,61		Algorithm converged.	0,71	3,64
	ARTHRALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5	0,78		Algorithm converged.	0,17	3,53	-0,003		Algorithm converged.	-0,023	0,016		0,78		Algorithm converged.	0,18	3,47	0,7494		1,27		Algorithm converged.	0,29	5,64
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	13	1,4	0,47		Algorithm converged.	0,18	1,23	-0,008		Algorithm converged.	-0,017	0,002		0,47		Algorithm converged.	0,18	1,23	0,1231		2,13		Algorithm converged.	0,81	5,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	BACK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	BONE PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,004		Algorithm converged.	-0,010	0,001	0,20		Algorithm converged.	0,02	1,74	0,1453		4,92		Algorithm converged.	0,58	42,05

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERVERTEBRAL DISC PROTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUSCULAR WEAKNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MUSCULOSKELETAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	MYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	11	1,2	0,64		Algorithm converged.	0,25	1,67	-0,004		Algorithm converged.	-0,013	0,005	0,65		Algorithm converged.	0,25	1,66	0,3645		1,55		Algorithm converged.	0,60	3,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	6	1,0	0,69		Algorithm converged.	0,19	2,46	-0,003		Algorithm converged.	-0,013	0,007		0,69		Algorithm converged.	0,20	2,44	0,5667		1,45		Algorithm converged.	0,41	5,10
	PAIN IN EXTREMITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RHEUMATOID ARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SJOGREN'S SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SPINAL OSTEOARTHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996293 9 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SPINAL STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002	0,25		Algorithm converged.	0,03	2,27	0,2198		3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BASAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST CANCER IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LENTIGO MALIGNA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONOCLONAL GAMMOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PAPILLARY THYROID CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	UTERINE LEIOMYOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082	0,66		Algorithm converged.	0,19	2,30	0,5128	-	1,52		Algorithm converged.	0,43	5,30						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	10	3,9	271	14,9	9	3,3	1,17		Algorithm converged.	0,47	2,93	0,005		Algorithm converged.	-0,026	0,037	1,16		Algorithm converged.	0,48	2,81	0,7385		0,86		Algorithm converged.	0,36	2,08
		1-3 positive nodes	891	50,0	37	4,2	905	49,7	27	3,0	1,41		Algorithm converged.	0,85	2,33	0,012		Algorithm converged.	-0,005	0,029	1,39		Algorithm converged.	0,85	2,27	0,1836		0,72		Algorithm converged.	0,44	1,17
		>= 4 positive nodes	582	32,6	23	4,0	604	33,2	17	2,8	1,42		Algorithm converged.	0,75	2,69	0,011		Algorithm converged.	-0,009	0,032	1,40		Algorithm converged.	0,76	2,60	0,2806		0,71		Algorithm converged.	0,38	1,32
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BURNING SENSATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARPAL TUNNEL SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL RADICULOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	DIZZINESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSGEUSIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003		0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71	
	INTERCOSTAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LETHARGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 34.259950313 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,069		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	MIGRAINE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROPATHY PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	7	0,8	0,14		Algorithm converged.	0,02	1,17	-0,007		Algorithm converged.	-0,013	0,000	0,15		Algorithm converged.	0,02	1,18	0,0707		6,89		Algorithm converged.	0,85	55,90
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	3	0,5	1,39		Algorithm converged.	0,31	6,22	0,002		Algorithm converged.	-0,007	0,011	1,38		Algorithm converged.	0,31	6,16	0,6698		0,72		Algorithm converged.	0,16	3,21
	NEUROTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PARAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455			0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 22.861526165 is greater than the limit of 0.0001. The convergence is questionable.	-0,041	0,096		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	PERIPHERAL MOTOR NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIPHERAL SENSORY NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	5	0,6	1,43		Algorithm converged.	0,45	4,51	0,002		Algorithm converged.	-0,005	0,010	1,42		Algorithm converged.	0,45	4,46	0,5464		0,70		Algorithm converged.	0,22	2,21
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	1	0,2	4,17		Algorithm converged.	0,47	37,45	0,005		Algorithm converged.	-0,002	0,013	4,15		Algorithm converged.	0,47	37,03	0,2024		0,24		Algorithm converged.	0,03	2,15
	POLYNEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PRESYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SCIATICA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015		1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	6	0,7	1,19		Algorithm converged.	0,40	3,54	0,001		Algorithm converged.	-0,007	0,009		1,18		Algorithm converged.	0,40	3,51	0,7595		0,84		Algorithm converged.	0,28	2,50
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	4	0,7	1,83		Algorithm converged.	0,53	6,27	0,005		Algorithm converged.	-0,006	0,016		1,82		Algorithm converged.	0,53	6,17	0,3390		0,55		Algorithm converged.	0,16	1,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THALAMIC INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	TRANSIENT ISCHAEMIC ATTACK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE			
PRODUCT ISSUE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE EXTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011	1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	EMOTIONAL DISTRESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INSOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4	3,16		Algorithm converged.	0,33	30,61	0,008		Algorithm converged.	-0,007	0,023	3,14		Algorithm converged.	0,33	29,98	0,3205		0,32		Algorithm converged.	0,03	3,04

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MAJOR DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	3	0,5	2,09		Algorithm converged.	0,52	8,38	0,005		Algorithm converged.	-0,005	0,015	2,08		Algorithm converged.	0,52	8,26	0,3001		0,48		Algorithm converged.	0,12	1,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247			0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLADDER PROLAPSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEPHROLITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URINARY TRACT OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	3	1,1	1,76		Algorithm converged.	0,42	7,43	0,008		Algorithm converged.	-0,013	0,029	1,74		Algorithm converged.	0,42	7,22	0,4431		0,57		Algorithm converged.	0,14	2,38
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	21	2,3	0,82		Algorithm converged.	0,43	1,56	-0,004		Algorithm converged.	-0,017	0,009	0,82		Algorithm converged.	0,44	1,55	0,5443		1,22		Algorithm converged.	0,65	2,29
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	13	2,2	0,71		Algorithm converged.	0,30	1,68	-0,006		Algorithm converged.	-0,021	0,009	0,72		Algorithm converged.	0,31	1,67	0,4417		1,39		Algorithm converged.	0,60	3,23

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AMENORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	4	0,4	1,27		Algorithm converged.	0,34	4,75	0,001		Algorithm converged.	-0,005	0,008		1,27		Algorithm converged.	0,34	4,71	0,7213		0,79		Algorithm converged.	0,21	2,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002		0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
	BREAST HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HEAVY MENSTRUAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENSTRUATION IRREGULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	14	1,5	0,80		Algorithm converged.	0,36	1,76	-0,003		Algorithm converged.	-0,014	0,008	0,80		Algorithm converged.	0,36	1,75	0,5729		1,25		Algorithm converged.	0,57	2,75
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	6	1,0	0,52		Algorithm converged.	0,13	2,07	-0,005		Algorithm converged.	-0,015	0,005	0,52		Algorithm converged.	0,13	2,07	0,3519		1,93		Algorithm converged.	0,48	7,67
	PREMATURE MENOPAUSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VAGINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVOVAGINAL DRYNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VULVOVAGINAL PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	3	1,1	2,85		Algorithm converged.	0,75	10,85	0,020		Algorithm converged.	-0,005	0,044		2,79		Algorithm converged.	0,75	10,40	0,1264		0,36		Algorithm converged.	0,10	1,34
		1-3 positive nodes	891	50,0	11	1,2	905	49,7	10	1,1	1,12		Algorithm converged.	0,47	2,65	0,001		Algorithm converged.	-0,009	0,011		1,12		Algorithm converged.	0,48	2,62	0,7985		0,90		Algorithm converged.	0,38	2,10
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	8	1,3	0,39		Algorithm converged.	0,10	1,46	-0,008		Algorithm converged.	-0,019	0,003		0,39		Algorithm converged.	0,10	1,46	0,1618		2,57		Algorithm converged.	0,69	9,64
	ACUTE RESPIRATORY DISTRESS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASTHMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CATARRH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,003		Algorithm converged.	-0,009	0,002		0,41		Algorithm converged.	0,08	2,09	0,2809		2,46		Algorithm converged.	0,48	12,65
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002		0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPISTAXIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	PLEURAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PNEUMOTHORAX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	RHINORRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHEEZING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056	0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	13	5,0	271	14,9	5	1,8	2,81		Algorithm converged.	0,99	8,00	0,032		Algorithm converged.	0,001	0,063	2,72		Algorithm converged.	0,98	7,52	0,0538		0,37		Algorithm converged.	0,13	1,02
		1-3 positive nodes	891	50,0	35	3,9	905	49,7	18	2,0	2,01		Algorithm converged.	1,13	3,58	0,019		Algorithm converged.	0,004	0,035	1,97		Algorithm converged.	1,13	3,46	0,0174		0,51		Algorithm converged.	0,29	0,89
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	12	2,0	1,22		Algorithm converged.	0,56	2,65	0,004		Algorithm converged.	-0,013	0,021	1,21		Algorithm converged.	0,56	2,60	0,6230		0,83		Algorithm converged.	0,39	1,77
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ALOPECIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANGIOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BLISTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATITIS ACNEIFORM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE GENERALISED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRY SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EXFOLIATIVE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGROWING NAIL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL BED INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NAIL DISCOLOURATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAIL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	2	0,2	1,53		Algorithm converged.	0,25	9,15	0,001		Algorithm converged.	-0,004	0,006	1,52		Algorithm converged.	0,26	9,10	0,6442		0,66		Algorithm converged.	0,11	3,92

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NAIL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NIGHT SWEATS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ONYCHOCLASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ONYCHOMADESIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	3	1,1	2,12		Algorithm converged.	0,52	8,56	0,012		Algorithm converged.	-0,010	0,034		2,09		Algorithm converged.	0,53	8,28	0,2927		0,48		Algorithm converged.	0,12	1,89
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	2	0,2	4,61		Algorithm converged.	0,99	21,38	0,008		Algorithm converged.	0,001	0,015		4,57		Algorithm converged.	0,99	21,10	0,0515		0,22		Algorithm converged.	0,05	1,01
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	1	0,2	5,23		Algorithm converged.	0,61	44,86	0,007		Algorithm converged.	-0,001	0,015		5,19		Algorithm converged.	0,61	44,28	0,1323		0,19		Algorithm converged.	0,02	1,64
	PHOTOSENSITIVITY REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PSORIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008	4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	RASH MACULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RASH MACULO-PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SCAR PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN EXFOLIATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SKIN IRRITATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SKIN LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
	SKIN REACTION	0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TOXIC SKIN ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST RECONSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	5	1,8	1,70		Algorithm converged.	0,55	5,25	0,012		Algorithm converged.	-0,014	0,039		1,67		Algorithm converged.	0,55	5,05	0,3604		0,60		Algorithm converged.	0,20	1,80
		1-3 positive nodes	891	50,0	15	1,7	905	49,7	33	3,6	0,45		Algorithm converged.	0,24	0,84	-0,020		Algorithm converged.	-0,034	-0,005		0,46		Algorithm converged.	0,25	0,84	0,0120		2,17		Algorithm converged.	1,18	3,96
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	15	2,5	0,97		Algorithm converged.	0,46	2,02	-0,001		Algorithm converged.	-0,018	0,017		0,97		Algorithm converged.	0,47	1,99	0,9308		1,03		Algorithm converged.	0,50	2,12
	AXILLARY VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DEEP VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37
	EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HOT FLUSH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	6	0,7	0,34		Algorithm converged.	0,07	1,67	-0,004		Algorithm converged.	-0,011	0,002	0,34		Algorithm converged.	0,07	1,67	0,1840		2,95		Algorithm converged.	0,60	14,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918			1,93		Algorithm converged.	0,18	21,20
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-		1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	7	2,7	271	14,9	2	0,7	3,74		Algorithm converged.	0,77	18,15	0,020		Algorithm converged.	-0,003	0,042		3,66		Algorithm converged.	0,77	17,47	0,1034			0,27		Algorithm converged.	0,06	1,30
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	19	2,1	0,42		Algorithm converged.	0,18	0,97	-0,012		Algorithm converged.	-0,023	-0,001		0,43		Algorithm converged.	0,19	0,97	0,0425			2,34		Algorithm converged.	1,03	5,31
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	10	1,7	0,72		Algorithm converged.	0,27	1,91	-0,005		Algorithm converged.	-0,018	0,009		0,73		Algorithm converged.	0,28	1,90	0,5137			1,38		Algorithm converged.	0,53	3,59
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	4	0,4	0,25		Algorithm converged.	0,03	2,27	-0,003		Algorithm converged.	-0,008	0,002		0,25		Algorithm converged.	0,03	2,27	0,2198			3,94		Algorithm converged.	0,44	35,17
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	JUGULAR VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ORTHOSTATIC HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE			
	SUBCLAVIAN VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		-	NE		Algorithm converged.	NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUPERIOR VENA CAVA OCCLUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOPHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENOUS THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR3_S1.xls
05MAY2022 17:21

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	235	13,2	1822	100,0	222	12,2	1,09		Algorithm converged.	0,90	1,33	0,010		Algorithm converged.	-0,012	0,032	1,08		Algorithm converged.	0,91	1,28	0,3692		0,92		Algorithm converged.	0,78	1,10
	AGRANULOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	FEBRILE NEUTROPENIA	n/a	1783	100,0	59	3,3	1822	100,0	50	2,7	1,21		Algorithm converged.	0,83	1,78	0,006		Algorithm converged.	-0,006	0,017	1,21		Algorithm converged.	0,83	1,75	0,3229		0,83		Algorithm converged.	0,57	1,20
	GRANULOCYTOPENIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	LEUKOPENIA	n/a	1783	100,0	19	1,1	1822	100,0	32	1,8	0,60		Algorithm converged.	0,34	1,07	-0,007		Algorithm converged.	-0,015	0,001	0,61		Algorithm converged.	0,35	1,07	0,0824		1,65		Algorithm converged.	0,94	2,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYELOSUPPRESSION	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27
	NEUTROPENIA	n/a	1783	100,0	171	9,6	1822	100,0	151	8,3	1,17		Algorithm converged.	0,93	1,48	0,013		Algorithm converged.	-0,006	0,032	1,16		Algorithm converged.	0,94	1,43	0,1707		0,86		Algorithm converged.	0,70	1,06

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
CARDIAC DISORDER	-Total	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1	2,56		Algorithm converged.	0,50	13,21	0,002		Algorithm converged.	-0,001	0,005	2,55		Algorithm converged.	0,50	13,15	0,2619		0,39		Algorithm converged.	0,08	2,01

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIAC FAILURE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERICARDIAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STRESS CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	7	0,4	1822	100,0	3	0,2	2,39		Algorithm converged.	0,62	9,26	0,002		Algorithm converged.	-0,001	0,006	2,38		Algorithm converged.	0,62	9,21	0,2074		0,42		Algorithm converged.	0,11	1,62
	COLITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL INTESTINAL OBSTRUCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ASTHENIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERSENSITIVITY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	13	0,7	1822	100,0	18	1,0	0,74		Algorithm converged.	0,36	1,51	-0,003		Algorithm converged.	-0,009	0,003	0,74		Algorithm converged.	0,36	1,50	0,4019		1,35		Algorithm converged.	0,67	2,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE HEPATITIS B	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CELLULITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS INTESTINAL PERFORATED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428966 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPSIS	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	UROSEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INVESTIGATION	-Total	n/a	1783	100,0	124	7,0	1822	100,0	129	7,1	0,98		Algorithm converged.	0,76	1,27	-0,001		Algorithm converged.	-0,018	0,015	0,98		Algorithm converged.	0,77	1,25	0,8827		1,02		Algorithm converged.	0,80	1,29

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD CREATININE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOCYTE COUNT DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	110	6,2	1822	100,0	111	6,1	1,01		Algorithm converged.	0,77	1,33	0,001		Algorithm converged.	-0,015	0,016	1,01		Algorithm converged.	0,78	1,31	0,9231		0,99		Algorithm converged.	0,76	1,27
	PLATELET COUNT DECREASED	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	16	0,9	1822	100,0	13	0,7	1,26		Algorithm converged.	0,60	2,63	0,002		Algorithm converged.	-0,004	0,008	1,26		Algorithm converged.	0,61	2,61	0,5376		0,80		Algorithm converged.	0,38	1,65
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	11	0,6	1822	100,0	8	0,4	1,41		Algorithm converged.	0,56	3,51	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,48	0,4631		0,71		Algorithm converged.	0,29	1,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEHYDRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ELECTROLYTE IMBALANCE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRIGLYCERIDAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOCALCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005	2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOMAGNESAEMIA	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,022	*	WARNING: The relative Hessian convergence criterion of 38.204428716 is greater than the limit of 0.0001. The convergence is questionable.	-0,028	0,072	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPONATRAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OBESITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMORRHAGE INTRACRANIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SYNCOPE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	ANXIETY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENTAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOTIC DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDAL IDEATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDE ATTEMPT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	ACUTE KIDNEY INJURY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL IMPAIRMENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETERIC OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOXIC EPIDERMAL NECROLYSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
VASCULAR DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMBOLISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTENSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR4_S1.xls

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

05MAY2022 18:19

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	205	13,1	1601	87,9	187	11,7	1,14		Algorithm converged.	0,92	1,41	0,014		Algorithm converged.	-0,009	0,037	1,12		Algorithm converged.	0,93	1,35	0,2233	0,2939	0,89		Algorithm converged.	0,74	1,07
		>= 65	219	12,3	30	13,7	221	12,1	35	15,8	0,84		Algorithm converged.	0,50	1,43	-0,021		Algorithm converged.	-0,088	0,045	0,86		Algorithm converged.	0,55	1,36	0,5279		1,16		Algorithm converged.	0,74	1,81
	AGRANULOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	50	3,2	1601	87,9	42	2,6	1,23		Algorithm converged.	0,81	1,86	0,006		Algorithm converged.	-0,006	0,017	1,22		Algorithm converged.	0,81	1,83	0,3377	0,8915	0,82		Algorithm converged.	0,55	1,23
		>= 65	219	12,3	9	4,1	221	12,1	8	3,6	1,14		Algorithm converged.	0,43	3,01	0,005		Algorithm converged.	-0,031	0,041	1,14		Algorithm converged.	0,45	2,89	0,7900		0,88		Algorithm converged.	0,35	2,24

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRANULOCYTOPENIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOPENIA	< 65	1564	87,7	18	1,2	1601	87,9	25	1,6	0,73		Algorithm converged.	0,40	1,35	-0,004		Algorithm converged.	-0,012	0,004	0,74		Algorithm converged.	0,40	1,35	0,3204	-	1,36		Algorithm converged.	0,74	2,48
		>= 65	219	12,3	1	0,5	221	12,1	7	3,2	0,14		Algorithm converged.	0,02	1,15	-0,027		Algorithm converged.	-0,052	-0,002	0,14		Algorithm converged.	0,02	1,16	0,0689		6,94		Algorithm converged.	0,86	55,91
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	< 65	1564	87,7	150	9,6	1601	87,9	127	7,9	1,23		Algorithm converged.	0,96	1,58	0,017		Algorithm converged.	-0,003	0,036	1,21		Algorithm converged.	0,96	1,52	0,0995	0,3033	0,83		Algorithm converged.	0,66	1,04
		>= 65	219	12,3	21	9,6	221	12,1	24	10,9	0,87		Algorithm converged.	0,47	1,62	-0,013		Algorithm converged.	-0,069	0,044	0,88		Algorithm converged.	0,51	1,54	0,6604		1,13		Algorithm converged.	0,65	1,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	< 65	1564	87,7	4	0,3	1601	87,9	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7655	-	1,22		Algorithm converged.	0,33	4,54
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36
CARDIAC DISORDER	-Total	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PERICARDIAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	STRESS CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	VENTRICULAR FIBRILLATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	COLITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ASTHENIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	8	0,5	1601	87,9	14	0,9	0,58		Algorithm converged.	0,24	1,39	-0,004		Algorithm converged.	-0,009	0,002	0,58		Algorithm converged.	0,25	1,39	0,2248	-	1,71		Algorithm converged.	0,72	4,06
		>= 65	219	12,3	5	2,3	221	12,1	4	1,8	1,27		Algorithm converged.	0,34	4,78	0,005		Algorithm converged.	-0,022	0,031	1,26		Algorithm converged.	0,34	4,64	0,7265		0,79		Algorithm converged.	0,22	2,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE HEPATITIS B	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS INTESTINAL PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963341 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	RECTAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	< 65	1564	87,7	3	0,2	1601	87,9	6	0,4	0,51		Algorithm converged.	0,13	2,05	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,13	2,04	0,3429	-	1,95		Algorithm converged.	0,49	7,80
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	< 65	1564	87,7	106	6,8	1601	87,9	114	7,1	0,95		Algorithm converged.	0,72	1,25	-0,003		Algorithm converged.	-0,021	0,014	0,95		Algorithm converged.	0,74	1,23	0,7044	0,5034	1,05		Algorithm converged.	0,81	1,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL					
		>= 65	219	12,3	18	8,2	221	12,1	15	6,8	1,23		Algorithm converged.	0,60	2,51	0,014		Algorithm converged.	-0,035	0,064	1,21		Algorithm converged.	0,63	2,34	0,5693		0,83		Algorithm converged.	0,43	1,60					
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE					
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE					
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CHOLESTEROL INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	LYMPHOCYTE COUNT DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPHIL COUNT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	96	6,1	1601	87,9	100	6,2	0,98		Algorithm converged.	0,74	1,31	-0,001		Algorithm converged.	-0,018	0,016	0,98		Algorithm converged.	0,75	1,29	0,8997	0,5176	1,02		Algorithm converged.	0,78	1,33
		>= 65	219	12,3	14	6,4	221	12,1	11	5,0	1,30		Algorithm converged.	0,58	2,94	0,014		Algorithm converged.	-0,029	0,057	1,28		Algorithm converged.	0,60	2,77	0,5226		0,78		Algorithm converged.	0,36	1,68
	PLATELET COUNT DECREASED	< 65	1564	87,7	2	0,1	1601	87,9	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4389	-	1,95		Algorithm converged.	0,36	10,65

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHITE BLOOD CELL COUNT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	10	0,6	1601	87,9	12	0,7	0,85		Algorithm converged.	0,37	1,98	-0,001		Algorithm converged.	-0,007	0,005	0,85		Algorithm converged.	0,37	1,97	0,7095	-	1,17		Algorithm converged.	0,51	2,71
		>= 65	219	12,3	6	2,7	221	12,1	1	0,5	6,20		Algorithm converged.	0,74	51,91	0,023		Algorithm converged.	0,000	0,046	6,05		Algorithm converged.	0,73	49,88	0,0942		0,17		Algorithm converged.	0,02	1,36
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	6	0,4	1601	87,9	6	0,4	1,02		Algorithm converged.	0,33	3,18	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,33	3,17	0,9676	-	0,98		Algorithm converged.	0,32	3,02
		>= 65	219	12,3	5	2,3	221	12,1	2	0,9	2,56		Algorithm converged.	0,49	13,33	0,014		Algorithm converged.	-0,010	0,037	2,52		Algorithm converged.	0,49	12,87	0,2656		0,40		Algorithm converged.	0,08	2,02

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEHYDRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROLYTE IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTRIGLYCERIDAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOMAGNESAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPONATRAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OBESITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHAGE INTRACRANIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANXIETY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	DEPRESSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MENTAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSYCHOTIC DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDAL IDEATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE KIDNEY INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL IMPAIRMENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	PULMONARY OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR4_S1.xls
05MAY2022 18:19

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	34	13,0	252	13,8	26	10,3	1,30		Algorithm converged.	0,75	2,23	0,027		Algorithm converged.	-0,029	0,082	1,26		Algorithm converged.	0,78	2,03	0,3495	-	0,80		Algorithm converged.	0,49	1,29
		Western Europe	814	45,7	104	12,8	824	45,2	98	11,9	1,09		Algorithm converged.	0,81	1,46	0,009		Algorithm converged.	-0,023	0,041	1,07		Algorithm converged.	0,83	1,39	0,5869		0,93		Algorithm converged.	0,72	1,21
		Asia Pacific	482	27,0	69	14,3	517	28,4	70	13,5	1,07		Algorithm converged.	0,75	1,53	0,008		Algorithm converged.	-0,035	0,051	1,06		Algorithm converged.	0,78	1,44	0,7234		0,95		Algorithm converged.	0,69	1,29
		Latin America	42	2,4	4	9,5	45	2,5	5	11,1	0,84		Algorithm converged.	0,21	3,37	-0,016		Algorithm converged.	-0,144	0,112	0,86		Algorithm converged.	0,25	2,98	0,8084		1,17		Algorithm converged.	0,34	4,05
		Other	183	10,3	24	13,1	184	10,1	23	12,5	1,06		Algorithm converged.	0,57	1,95	0,006		Algorithm converged.	-0,062	0,075	1,05		Algorithm converged.	0,62	1,79	0,8601		0,95		Algorithm converged.	0,56	1,63
	AGRANULOCYTOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
	BLOOD DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE					
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE					
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE					
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	5	0,6	824	45,2	4	0,5	1,27		Algorithm converged.	0,34	4,74	0,001		Algorithm converged.	-0,006	0,008		1,27		Algorithm converged.	0,34	4,70	0,7250		0,79		Algorithm converged.	0,21	2,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	8	3,1	252	13,8	5	2,0	1,56		Algorithm converged.	0,50	4,82	0,011		Algorithm converged.	-0,016	0,038		1,54		Algorithm converged.	0,51	4,64	0,4440	-	0,65		Algorithm converged.	0,22	1,96
		Western Europe	814	45,7	26	3,2	824	45,2	24	2,9	1,10		Algorithm converged.	0,63	1,93	0,003		Algorithm converged.	-0,014	0,019		1,10		Algorithm converged.	0,64	1,89	0,7407		0,91		Algorithm converged.	0,53	1,57
		Asia Pacific	482	27,0	17	3,5	517	28,4	13	2,5	1,42		Algorithm converged.	0,68	2,95	0,010		Algorithm converged.	-0,011	0,031		1,40		Algorithm converged.	0,69	2,86	0,3512		0,71		Algorithm converged.	0,35	1,45
		Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091		1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
		Other	183	10,3	6	3,3	184	10,1	6	3,3	1,01		Algorithm converged.	0,32	3,18	0,000		Algorithm converged.	-0,036	0,037		1,01		Algorithm converged.	0,33	3,06	0,9923		0,99		Algorithm converged.	0,33	3,03
	GRANULOCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005		0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LEUKOPENIA	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015		0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32
		Western Europe	814	45,7	6	0,7	824	45,2	12	1,5	0,50		Algorithm converged.	0,19	1,35	-0,007		Algorithm converged.	-0,017	0,003		0,51		Algorithm converged.	0,19	1,34	0,1711		1,98		Algorithm converged.	0,75	5,24
		Asia Pacific	482	27,0	9	1,9	517	28,4	15	2,9	0,64		Algorithm converged.	0,28	1,47	-0,010		Algorithm converged.	-0,029	0,009		0,64		Algorithm converged.	0,28	1,46	0,2904		1,55		Algorithm converged.	0,69	3,52

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013		1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	USA/Canada	262	14,7	24	9,2	252	13,8	19	7,5	1,24		Algorithm converged.	0,66	2,32	0,016		Algorithm converged.	-0,032	0,064		1,21		Algorithm converged.	0,68	2,16	0,5080	-	0,82		Algorithm converged.	0,46	1,46
		Western Europe	814	45,7	75	9,2	824	45,2	64	7,8	1,21		Algorithm converged.	0,85	1,71	0,014		Algorithm converged.	-0,013	0,041		1,19		Algorithm converged.	0,86	1,63	0,2942		0,84		Algorithm converged.	0,61	1,16
		Asia Pacific	482	27,0	52	10,8	517	28,4	49	9,5	1,16		Algorithm converged.	0,77	1,74	0,013		Algorithm converged.	-0,024	0,051		1,14		Algorithm converged.	0,79	1,65	0,4926		0,88		Algorithm converged.	0,61	1,27
		Latin America	42	2,4	3	7,1	45	2,5	3	6,7	1,08		Algorithm converged.	0,21	5,66	0,005		Algorithm converged.	-0,102	0,111		1,07		Algorithm converged.	0,23	5,02	0,9302		0,93		Algorithm converged.	0,20	4,37
		Other	183	10,3	17	9,3	184	10,1	16	8,7	1,08		Algorithm converged.	0,53	2,20	0,006		Algorithm converged.	-0,053	0,064		1,07		Algorithm converged.	0,56	2,05	0,8424		0,94		Algorithm converged.	0,49	1,80
	PANCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	USA/Canada	262	14,7	2	0,8	252	13,8	4	1,6	0,48		Algorithm converged.	0,09	2,63	-0,008		Algorithm converged.	-0,027	0,010		0,48		Algorithm converged.	0,09	2,60	0,3955	-	2,08		Algorithm converged.	0,38	11,25
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRADYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERICARDIAL EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STRESS CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SMALL INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	ASTHENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026		1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	5	0,6	824	45,2	7	0,8	0,72		Algorithm converged.	0,23	2,28	-0,002		Algorithm converged.	-0,011	0,006		0,72		Algorithm converged.	0,23	2,27	0,5784		1,38		Algorithm converged.	0,44	4,34
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009		0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE HEPATITIS B	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DEVICE RELATED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DIVERTICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DIVERTICULITIS INTESTINAL PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	NEUTROPENIC SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RECTAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPSIS	USA/Canada	262	14,7	4	1,5	252	13,8	2	0,8	1,94		Algorithm converged.	0,35	10,68	0,007		Algorithm converged.	-0,011	0,026	1,92		Algorithm converged.	0,36	10,41	0,4476	-	0,52		Algorithm converged.	0,10	2,81
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5	0,25		Algorithm converged.	0,03	2,26	-0,004		Algorithm converged.	-0,009	0,002	0,25		Algorithm converged.	0,03	2,26	0,2186		3,95		Algorithm converged.	0,44	35,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UROSEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	USA/Canada	262	14,7	10	3,8	252	13,8	11	4,4	0,87		Algorithm converged.	0,36	2,08	-0,005		Algorithm converged.	-0,040	0,029	0,87		Algorithm converged.	0,38	2,02	0,7538	-	1,14		Algorithm converged.	0,49	2,65
		Western Europe	814	45,7	27	3,3	824	45,2	34	4,1	0,80		Algorithm converged.	0,48	1,33	-0,008		Algorithm converged.	-0,026	0,010	0,80		Algorithm converged.	0,49	1,32	0,3882		1,24		Algorithm converged.	0,76	2,04
		Asia Pacific	482	27,0	85	17,6	517	28,4	81	15,7	1,15		Algorithm converged.	0,83	1,61	0,020		Algorithm converged.	-0,027	0,066	1,13		Algorithm converged.	0,85	1,49	0,4041		0,89		Algorithm converged.	0,67	1,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CHOLESTEROL INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHOCYTE COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	8	3,1	252	13,8	9	3,6	0,85		Algorithm converged.	0,32	2,24	-0,005		Algorithm converged.	-0,036	0,026	0,85		Algorithm converged.	0,34	2,18	0,7430	-	1,17		Algorithm converged.	0,46	2,98
		Western Europe	814	45,7	20	2,5	824	45,2	24	2,9	0,84		Algorithm converged.	0,46	1,53	-0,005		Algorithm converged.	-0,020	0,011	0,84		Algorithm converged.	0,47	1,51	0,5690		1,19		Algorithm converged.	0,66	2,13
		Asia Pacific	482	27,0	81	16,8	517	28,4	76	14,7	1,17		Algorithm converged.	0,83	1,65	0,021		Algorithm converged.	-0,024	0,066	1,14		Algorithm converged.	0,86	1,52	0,3614		0,87		Algorithm converged.	0,66	1,17
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	2	1,1	0,50		Algorithm converged.	0,04	5,56	-0,005		Algorithm converged.	-0,024	0,013	0,50		Algorithm converged.	0,05	5,50	0,5731		1,99		Algorithm converged.	0,18	21,75

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	7	0,8	0,72		Algorithm converged.	0,23	2,28	-0,002		Algorithm converged.	-0,011	0,006	0,72		Algorithm converged.	0,23	2,27	0,5784		1,38		Algorithm converged.	0,44	4,34
		Asia Pacific	482	27,0	9	1,9	517	28,4	6	1,2	1,62		Algorithm converged.	0,57	4,59	0,007		Algorithm converged.	-0,008	0,022	1,61		Algorithm converged.	0,58	4,49	0,3634		0,62		Algorithm converged.	0,22	1,73
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	7	2,7	252	13,8	2	0,8	3,43		Algorithm converged.	0,71	16,68	0,019		Algorithm converged.	-0,004	0,041	3,37		Algorithm converged.	0,71	16,05	0,1277	-	0,30		Algorithm converged.	0,06	1,42
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	4	0,8	0,27		Algorithm converged.	0,03	2,39	-0,006		Algorithm converged.	-0,014	0,003	0,27		Algorithm converged.	0,03	2,39	0,2383		3,73		Algorithm converged.	0,42	33,25
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DEHYDRATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROLYTE IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERGLYCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011		0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPONATRAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OBESITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	1	0,1	4,06		Algorithm converged.	0,45	36,44	0,004		Algorithm converged.	-0,002	0,009	4,05		Algorithm converged.	0,45	36,15	0,2105		0,25		Algorithm converged.	0,03	2,20
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SYNCOPE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005		2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANXIETY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOTIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RENAL IMPAIRMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HYPERTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HYPOTENSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR4_S1.xls
05MAY2022 18:19

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	8	15,7	42	2,3	4	9,5	1,77		Algorithm converged.	0,49	6,34	0,062		Algorithm converged.	-0,072	0,195		1,65		Algorithm converged.	0,53	5,09	0,3862	0,5538	0,61		Algorithm converged.	0,20	1,88	
		0 positive nodes, tumor > 1 cm	259	14,5	35	13,5	271	14,9	33	12,2	1,13		Algorithm converged.	0,68	1,88	0,013		Algorithm converged.	-0,044	0,070		1,11		Algorithm converged.	0,71	1,73	0,6458		0,90		Algorithm converged.	0,58	1,40	
		1-3 positive nodes	891	50,0	121	13,6	905	49,7	105	11,6	1,20		Algorithm converged.	0,91	1,58	0,020		Algorithm converged.	-0,011	0,050		1,17		Algorithm converged.	0,92	1,49	0,2070		0,85		Algorithm converged.	0,67	1,09	
		>= 4 positive nodes	582	32,6	71	12,2	604	33,2	80	13,2	0,91		Algorithm converged.	0,65	1,28	-0,010		Algorithm converged.	-0,048	0,027		0,92		Algorithm converged.	0,68	1,24	0,5893		1,09		Algorithm converged.	0,81	1,46	
	AGRANULOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.33996 2958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,004	*	WARNING: The relative Hessian convergence criterion of 35.330573761 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,070	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20	
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	2	4,8	0,82		Algorithm converged.	0,11	6,06	-0,008		Algorithm converged.	-0,092	0,075	0,82		Algorithm converged.	0,12	5,60	0,8426	-	1,21		Algorithm converged.	0,18	8,26	
		0 positive nodes, tumor > 1 cm	259	14,5	8	3,1	271	14,9	8	3,0	1,05		Algorithm converged.	0,39	2,83	0,001		Algorithm converged.	-0,028	0,031	1,05		Algorithm converged.	0,40	2,75	0,9267		0,96		Algorithm converged.	0,36	2,51	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	32	3,6	905	49,7	24	2,7	1,37		Algorithm converged.	0,80	2,34	0,009		Algorithm converged.	-0,007	0,025	1,35		Algorithm converged.	0,80	2,28	0,2540		0,74		Algorithm converged.	0,44	1,24
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	16	2,6	1,11		Algorithm converged.	0,55	2,21	0,003		Algorithm converged.	-0,016	0,021	1,10		Algorithm converged.	0,56	2,16	0,7760		0,91		Algorithm converged.	0,46	1,78
	GRANULOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	6	2,2	0,34		Algorithm converged.	0,07	1,72	-0,014		Algorithm converged.	-0,035	0,006		0,35		Algorithm converged.	0,07	1,71	0,1945		2,87		Algorithm converged.	0,58	14,08
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	15	1,7	0,54		Algorithm converged.	0,23	1,27	-0,008		Algorithm converged.	-0,018	0,003		0,54		Algorithm converged.	0,23	1,27	0,1590		1,85		Algorithm converged.	0,79	4,33
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	11	1,8	0,75		Algorithm converged.	0,30	1,88	-0,004		Algorithm converged.	-0,019	0,010		0,75		Algorithm converged.	0,31	1,86	0,5417		1,32		Algorithm converged.	0,54	3,27
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	1	2,4	4,46		Algorithm converged.	0,50	39,74	0,074		Algorithm converged.	-0,020	0,168	4,12		Algorithm converged.	0,50	33,89	0,1882	-	0,24		Algorithm converged.	0,03	2,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	24	9,3	271	14,9	20	7,4	1,28		Algorithm converged.	0,69	2,38	0,019		Algorithm converged.	-0,028	0,066	1,26		Algorithm converged.	0,71	2,22	0,4326		0,80		Algorithm converged.	0,45	1,41
		1-3 positive nodes	891	50,0	90	10,1	905	49,7	78	8,6	1,19		Algorithm converged.	0,87	1,64	0,015		Algorithm converged.	-0,012	0,042	1,17		Algorithm converged.	0,88	1,56	0,2814		0,85		Algorithm converged.	0,64	1,14
		>= 4 positive nodes	582	32,6	52	8,9	604	33,2	52	8,6	1,04		Algorithm converged.	0,70	1,56	0,003		Algorithm converged.	-0,029	0,035	1,04		Algorithm converged.	0,72	1,50	0,8430		0,96		Algorithm converged.	0,67	1,39
	PANCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	4	0,7	0,26		Algorithm converged.	0,03	2,32	-0,005		Algorithm converged.	-0,012	0,002	0,26		Algorithm converged.	0,03	2,31	0,2269		3,85		Algorithm converged.	0,43	34,38
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801847 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRADYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801847 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERICARDIAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRESS CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010	5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 42.426716 29 is greater than the limit of 0.0001. The convergence is questionable.	-0,060	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UPPER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	9	1,0	0,67		Algorithm converged.	0,24	1,90	-0,003		Algorithm converged.	-0,012	0,005	0,68		Algorithm converged.	0,24	1,89	0,4577		1,48		Algorithm converged.	0,53	4,13
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	8	1,3	0,65		Algorithm converged.	0,21	1,98	-0,005		Algorithm converged.	-0,016	0,007	0,65		Algorithm converged.	0,21	1,97	0,4453		1,54		Algorithm converged.	0,51	4,69
	ACUTE HEPATITIS B	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS INTESTINAL PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 45.078386058 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,069		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	RECTAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	4	9,5	1,03		Algorithm converged.	0,26	4,12	0,003		Algorithm converged.	-0,118	0,123		1,03		Algorithm converged.	0,30	3,59	0,9637	-	0,97		Algorithm converged.	0,28	3,39
		0 positive nodes, tumor > 1 cm	259	14,5	28	10,8	271	14,9	22	8,1	1,37		Algorithm converged.	0,76	2,47	0,027		Algorithm converged.	-0,023	0,077		1,33		Algorithm converged.	0,78	2,27	0,2911		0,75		Algorithm converged.	0,44	1,28
		1-3 positive nodes	891	50,0	51	5,7	905	49,7	67	7,4	0,76		Algorithm converged.	0,52	1,11	-0,017		Algorithm converged.	-0,040	0,006		0,77		Algorithm converged.	0,54	1,10	0,1523		1,29		Algorithm converged.	0,91	1,84
		>= 4 positive nodes	582	32,6	40	6,9	604	33,2	36	6,0	1,16		Algorithm converged.	0,73	1,85	0,009		Algorithm converged.	-0,019	0,037		1,15		Algorithm converged.	0,75	1,78	0,5216		0,87		Algorithm converged.	0,56	1,34
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD CHOLESTEROL INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHOCYTE COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPHIL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	4	9,5	1,03		Algorithm converged.	0,26	4,12	0,003		Algorithm converged.	-0,118	0,123	1,03		Algorithm converged.	0,30	3,59	0,9637	-	0,97		Algorithm converged.	0,28	3,39
		0 positive nodes, tumor > 1 cm	259	14,5	25	9,7	271	14,9	22	8,1	1,21		Algorithm converged.	0,66	2,20	0,015		Algorithm converged.	-0,033	0,064	1,19		Algorithm converged.	0,69	2,05	0,5351		0,84		Algorithm converged.	0,49	1,45
		1-3 positive nodes	891	50,0	46	5,2	905	49,7	57	6,3	0,81		Algorithm converged.	0,54	1,21	-0,011		Algorithm converged.	-0,033	0,010	0,82		Algorithm converged.	0,56	1,20	0,3017		1,22		Algorithm converged.	0,84	1,78
		>= 4 positive nodes	582	32,6	34	5,8	604	33,2	28	4,6	1,28		Algorithm converged.	0,76	2,13	0,012		Algorithm converged.	-0,013	0,037	1,26		Algorithm converged.	0,77	2,05	0,3520		0,79		Algorithm converged.	0,49	1,29
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	WHITE BLOOD CELL COUNT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	9	1,0	0,67		Algorithm converged.	0,24	1,90	-0,003		Algorithm converged.	-0,012	0,005	0,68		Algorithm converged.	0,24	1,89	0,4577		1,48		Algorithm converged.	0,53	4,13
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	4	0,7	2,36		Algorithm converged.	0,72	7,69	0,009		Algorithm converged.	-0,003	0,021	2,34		Algorithm converged.	0,72	7,54	0,1562		0,43		Algorithm converged.	0,13	1,38
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	5	0,6	1,22		Algorithm converged.	0,37	4,01	0,001		Algorithm converged.	-0,006	0,008	1,22		Algorithm converged.	0,37	3,98	0,7430		0,82		Algorithm converged.	0,25	2,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROLYTE IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTRIGLYCERIDAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009		2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPONATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OBESITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TRANSITIONAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMORRHAGE INTRACRANIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE				NE	NE
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDE ATTEMPT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004		0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETERIC OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC EPIDERMAL NECROLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR4_S1.xls
05MAY2022 18:19

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE NEUTROPENIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTROINTESTINAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL ISCHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	PNEUMONIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA ASPIRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SEPTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ROAD TRAFFIC ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERKALAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ADENOCARCINOMA PANCREAS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTRIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL CELL LUNG CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)				Convergence Reason	95% Lower CL	95% Upper CL
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	INTERSTITIAL LUNG DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY FIBROSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR5_S1.xls
05MAY2022 18:29

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	COLITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	GASTROINTESTINAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INTESTINAL ISCHAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA ASPIRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEPTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERKALAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYELOID LEUKAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERSTITIAL LUNG DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR5_S1.xls
05MAY2022 18:29

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	GASTROINTESTINAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA ASPIRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HYPERKALAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYELOID LEUKAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADENOCARCINOMA PANCREAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL CELL LUNG CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERSTITIAL LUNG DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR5_S1.xls
05MAY2022 18:29

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PNEUMONIA ASPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SEPTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE MYELOID LEUKAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ADENOCARCINOMA PANCREAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTRIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SMALL CELL LUNG CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk									Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
	INTERSTITIAL LUNG DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AEGR5_S1.xls
05MAY2022 18:29

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	192	10,8	1822	100,0	186	10,2	1,06		Algorithm converged.	0,86	1,31	0,006		Algorithm converged.	-0,014	0,026	1,05		Algorithm converged.	0,87	1,28	0,5834		0,95		Algorithm converged.	0,78	1,15
	ANAEMIA	n/a	1783	100,0	8	0,4	1822	100,0	8	0,4	1,02		Algorithm converged.	0,38	2,73	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,38	2,72	0,9654		0,98		Algorithm converged.	0,37	2,60
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3	1,19		Algorithm converged.	0,40	3,56	0,001		Algorithm converged.	-0,003	0,005	1,19		Algorithm converged.	0,40	3,54	0,7516		0,84		Algorithm converged.	0,28	2,49
	FEBRILE NEUTROPENIA	n/a	1783	100,0	154	8,6	1822	100,0	143	7,8	1,11		Algorithm converged.	0,88	1,41	0,008		Algorithm converged.	-0,010	0,026	1,10		Algorithm converged.	0,88	1,37	0,3894		0,91		Algorithm converged.	0,73	1,13
	HAEMOLYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LEUKOPENIA	n/a	1783	100,0	3	0,2	1822	100,0	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,003	0,002	0,77		Algorithm converged.	0,17	3,42	0,7273		1,30		Algorithm converged.	0,29	5,82
	LYMPHADENOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYELOSUPPRESSION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	NEUTROPENIA	n/a	1783	100,0	18	1,0	1822	100,0	21	1,2	0,87		Algorithm converged.	0,46	1,65	-0,001		Algorithm converged.	-0,008	0,005	0,88		Algorithm converged.	0,47	1,64	0,6783		1,14		Algorithm converged.	0,61	2,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
CARDIAC DISORDER	-Total	n/a	1783	100,0	36	2,0	1822	100,0	29	1,6	1,27		Algorithm converged.	0,78	2,09	0,004		Algorithm converged.	-0,004	0,013	1,27		Algorithm converged.	0,78	2,06	0,3361		0,79		Algorithm converged.	0,49	1,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGINA PECTORIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ATRIAL FIBRILLATION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	ATRIAL THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CARDIAC FAILURE	n/a	1783	100,0	25	1,4	1822	100,0	13	0,7	1,98		Algorithm converged.	1,01	3,88	0,007		Algorithm converged.	0,000	0,014	1,97		Algorithm converged.	1,01	3,83	0,0471		0,51		Algorithm converged.	0,26	0,99
	CARDIAC FAILURE CONGESTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CORONARY ARTERY STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXTRASYSTOLES	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	METABOLIC CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MYOCARDIAL INFARCTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PALPITATIONS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERICARDIAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	SINUS NODE DYSFUNCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STRESS CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TACHYCARDIA PAROXYSMAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENTRICULAR FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYLORIC STENOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTERNAL EAR INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TYMPANIC MEMBRANE PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERTIGO	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
ENDOCRINE DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	GOITRE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTHYROIDISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THYROID DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	86	4,8	1822	100,0	56	3,1	1,60		Algorithm converged.	1,13	2,25	0,017		Algorithm converged.	0,005	0,030	1,57		Algorithm converged.	1,13	2,18	0,0075		0,64		Algorithm converged.	0,46	0,89
	ABDOMINAL PAIN	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2	1,71		Algorithm converged.	0,41	7,15	0,001		Algorithm converged.	-0,002	0,004	1,70		Algorithm converged.	0,41	7,12	0,4655		0,59		Algorithm converged.	0,14	2,45
	ABDOMINAL PAIN UPPER	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COLITIS	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.602723787 is greater than the limit of 0.0001. The convergence is questionable.	-0,049	0,044	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONSTIPATION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA	n/a	1783	100,0	41	2,3	1822	100,0	14	0,8	3,04		Algorithm converged.	1,65	5,60	0,015		Algorithm converged.	0,007	0,023	2,99		Algorithm converged.	1,64	5,47	0,0004		0,33		Algorithm converged.	0,18	0,61
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DUODENAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUODENAL ULCER HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTERITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ENTEROCOLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRIC ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC ULCER HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTRITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL TOXICITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROOESOPHAGEAL REFLUX DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHOIDAL HAEMORRHAGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHOIDS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ILEUS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INGUINAL HERNIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL ISCHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTESTINAL OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTUSSUSCEPTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NAUSEA	n/a	1783	100,0	10	0,6	1822	100,0	10	0,5	1,02		Algorithm converged.	0,42	2,46	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,43	2,45	0,9613		0,98		Algorithm converged.	0,41	2,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA MOUTH	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ORAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS ACUTE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RECTAL HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL INTESTINAL OBSTRUCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	n/a	1783	100,0	7	0,4	1822	100,0	1	<0.1	7,18		Algorithm converged.	0,88	58,40	0,003		Algorithm converged.	0,000	0,006	7,15		Algorithm converged.	0,88	58,08	0,0656		0,14		Algorithm converged.	0,02	1,14
	SUBILEUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	VOMITING	n/a	1783	100,0	13	0,7	1822	100,0	11	0,6	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,004	0,007	1,21		Algorithm converged.	0,54	2,69	0,6440		0,83		Algorithm converged.	0,37	1,84
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	45	2,5	1822	100,0	54	3,0	0,85		Algorithm converged.	0,57	1,27	-0,004		Algorithm converged.	-0,015	0,006	0,85		Algorithm converged.	0,58	1,26	0,4196		1,17		Algorithm converged.	0,79	1,73
	ASTHENIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	CHEST PAIN	n/a	1783	100,0	4	0,2	1822	100,0	6	0,3	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,004	0,002	0,68		Algorithm converged.	0,19	2,41	0,5516		1,47		Algorithm converged.	0,41	5,19
	CHILLS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FATIGUE	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2	1,02		Algorithm converged.	0,26	4,09	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,26	4,08	0,9756		0,98		Algorithm converged.	0,25	3,91
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	INFLUENZA LIKE ILLNESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MALAISE	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003	1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MUCOSAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NON-CARDIAC CHEST PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	OEDEMA PERIPHERAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYREXIA	n/a	1783	100,0	26	1,5	1822	100,0	37	2,0	0,71		Algorithm converged.	0,43	1,18	-0,006		Algorithm converged.	-0,014	0,003	0,72		Algorithm converged.	0,44	1,18	0,1918		1,39		Algorithm converged.	0,85	2,29

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	7	0,4	1822	100,0	3	0,2	2,39		Algorithm converged.	0,62	9,26	0,002		Algorithm converged.	-0,001	0,006	2,38		Algorithm converged.	0,62	9,21	0,2074		0,42		Algorithm converged.	0,11	1,62
	BILIARY COLIC	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLANGITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CHOLECYSTITIS ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DRUG-INDUCED LIVER INJURY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FUNCTION ABNORMAL	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	12	0,7	1822	100,0	8	0,4	1,54		Algorithm converged.	0,63	3,77	0,002		Algorithm converged.	-0,003	0,007	1,53		Algorithm converged.	0,63	3,74	0,3481		0,65		Algorithm converged.	0,27	1,59
	ANAPHYLACTIC REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2	0,34		Algorithm converged.	0,04	3,27	-0,001		Algorithm converged.	-0,003	0,001	0,34		Algorithm converged.	0,04	3,27	0,3508		2,94		Algorithm converged.	0,31	28,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPERSENSITIVITY	n/a	1783	100,0	7	0,4	1822	100,0	3	0,2	2,39		Algorithm converged.	0,62	9,26	0,002		Algorithm converged.	-0,001	0,006	2,38		Algorithm converged.	0,62	9,21	0,2074		0,42		Algorithm converged.	0,11	1,62
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	126	7,1	1822	100,0	112	6,1	1,16		Algorithm converged.	0,89	1,51	0,009		Algorithm converged.	-0,007	0,025	1,15		Algorithm converged.	0,90	1,47	0,2667		0,87		Algorithm converged.	0,68	1,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	ABSCESS ORAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE HEPATITIS B	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APPENDICITIS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APPENDICITIS PERFORATED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BACTERIAL INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST CELLULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	BRONCHITIS	n/a	1783	100,0	5	0,3	1822	100,0	1	<0.1	5,12		Algorithm converged.	0,60	43,88	0,002		Algorithm converged.	0,000	0,005	5,11		Algorithm converged.	0,60	43,69	0,1363		0,20		Algorithm converged.	0,02	1,67
	CELLULITIS	n/a	1783	100,0	14	0,8	1822	100,0	12	0,7	1,19		Algorithm converged.	0,55	2,59	0,001		Algorithm converged.	-0,004	0,007	1,19		Algorithm converged.	0,55	2,57	0,6538		0,84		Algorithm converged.	0,39	1,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHRONIC SINUSITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CLOSTRIDIUM COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2	1,36		Algorithm converged.	0,30	6,10	0,001		Algorithm converged.	-0,002	0,003	1,36		Algorithm converged.	0,31	6,08	0,6852		0,73		Algorithm converged.	0,16	3,27

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIARRHOEA INFECTIOUS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DISSEMINATED TUBERCULOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3	0,51		Algorithm converged.	0,13	2,04	-0,002		Algorithm converged.	-0,005	0,002		0,51		Algorithm converged.	0,13	2,04	0,3417		1,96		Algorithm converged.	0,49	7,81
	DIVERTICULITIS INTESTINAL PERFORATED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ERYSIPELAS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ESCHERICHIA INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROENTERITIS	n/a	1783	100,0	7	0,4	1822	100,0	1	<0.1	7,18		Algorithm converged.	0,88	58,40	0,003		Algorithm converged.	0,000	0,006	7,15		Algorithm converged.	0,88	58,08	0,0656		0,14		Algorithm converged.	0,02	1,14
	GASTROENTERITIS VIRAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEPATITIS B REACTIVATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES ZOSTER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INFECTED LYMPHOCELE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTED SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTION	n/a	1783	100,0	5	0,3	1822	100,0	6	0,3	0,85		Algorithm converged.	0,26	2,79	0,000		Algorithm converged.	-0,004	0,003	0,85		Algorithm converged.	0,26	2,79	0,7904		1,17		Algorithm converged.	0,36	3,84
	LARYNGITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOCALISED INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	LYMPHANGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.17056219 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASTITIS	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2	1,02		Algorithm converged.	0,21	5,07	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9788		0,98		Algorithm converged.	0,20	4,84
	NASOPHARYNGITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUTROPENIC INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.581 86164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC SEPSIS	n/a	1783	100,0	8	0,4	1822	100,0	3	0,2	2,73		Algorithm converged.	0,72	10,32	0,003		Algorithm converged.	-0,001	0,006	2,72		Algorithm converged.	0,72	10,25	0,1382		0,37		Algorithm converged.	0,10	1,38
	OTITIS MEDIA ACUTE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PARONYCHIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERIODONTITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERITONSILLAR ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PHLEBITIS INFECTIVE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLEURAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508736 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOCYSTIS JIROVECII PNEUMONIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONIA	n/a	1783	100,0	16	0,9	1822	100,0	21	1,2	0,78		Algorithm converged.	0,40	1,49	-0,003		Algorithm converged.	-0,009	0,004	0,78		Algorithm converged.	0,41	1,49	0,4484		1,28		Algorithm converged.	0,67	2,45
	PNEUMONIA ASPIRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMONIA PNEUMOCOCCAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POSTOPERATIVE WOUND INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSEUDOMONAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	SALPINGO-OOPHORITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SEPSIS	n/a	1783	100,0	5	0,3	1822	100,0	8	0,4	0,64		Algorithm converged.	0,21	1,95	-0,002		Algorithm converged.	-0,005	0,002	0,64		Algorithm converged.	0,21	1,95	0,4308		1,57		Algorithm converged.	0,51	4,78
	SEPTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUSITIS	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3	0,41		Algorithm converged.	0,08	2,11	-0,002		Algorithm converged.	-0,004	0,001	0,41		Algorithm converged.	0,08	2,10	0,2845		2,45		Algorithm converged.	0,48	12,59
	SOFT TISSUE INFECTION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	STAPHYLOCOCCAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STREPTOCOCCAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCUTANEOUS ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	5	0,3	1822	100,0	4	0,2	1,28		Algorithm converged.	0,34	4,77	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,75	0,7149		0,78		Algorithm converged.	0,21	2,91
	URINARY TRACT INFECTION	n/a	1783	100,0	6	0,3	1822	100,0	7	0,4	0,88		Algorithm converged.	0,29	2,61	0,000		Algorithm converged.	-0,004	0,003	0,88		Algorithm converged.	0,29	2,60	0,8114		1,14		Algorithm converged.	0,38	3,39
	UROSEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VARICELLA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR DEVICE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	VIRAL INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VULVAL ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WOUND INFECTION	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	24	1,3	1822	100,0	18	1,0	1,37		Algorithm converged.	0,74	2,53	0,004		Algorithm converged.	-0,003	0,011	1,36		Algorithm converged.	0,74	2,50	0,3184		0,73		Algorithm converged.	0,40	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACCIDENTAL OVERDOSE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AVULSION FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PROCEDURAL COMPLICATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CONCUSSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FALL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEMORAL NECK FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	FRACTURED SACRUM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GRAFT THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HUMERUS FRACTURE	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1	4,09		Algorithm converged.	0,46	36,67	0,002		Algorithm converged.	-0,001	0,004	4,09		Algorithm converged.	0,46	36,53	0,2077		0,24		Algorithm converged.	0,03	2,19
	ILIUM FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFUSION RELATED REACTION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	INTENTIONAL OVERDOSE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER LIMB FRACTURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOCONIOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX TRAUMATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PROCEDURAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY RADIATION INJURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RADIUS FRACTURE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ROAD TRAFFIC ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEROMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN LACERATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SPINAL COMPRESSION FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THERMAL BURN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TIBIA FRACTURE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXICITY TO VARIOUS AGENTS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND DEHISCENCE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	WRIST FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INVESTIGATION	-Total	n/a	1783	100,0	19	1,1	1822	100,0	13	0,7	1,50		Algorithm converged.	0,74	3,04	0,004		Algorithm converged.	-0,003	0,010	1,49		Algorithm converged.	0,74	3,01	0,2630		0,67		Algorithm converged.	0,33	1,35
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATININE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE FLUCTUATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EJECTION FRACTION DECREASED	n/a	1783	100,0	8	0,4	1822	100,0	4	0,2	2,05		Algorithm converged.	0,62	6,81	0,002		Algorithm converged.	-0,001	0,006	2,04		Algorithm converged.	0,62	6,77	0,2424		0,49		Algorithm converged.	0,15	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LIVER FUNCTION TEST INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	6	0,3	1822	100,0	3	0,2	2,05		Algorithm converged.	0,51	8,20	0,002		Algorithm converged.	-0,002	0,005	2,04		Algorithm converged.	0,51	8,16	0,3115		0,49		Algorithm converged.	0,12	1,95

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLATELET COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TROPONIN INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562 19 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	30	1,7	1822	100,0	13	0,7	2,38		Algorithm converged.	1,24	4,58	0,010		Algorithm converged.	0,003	0,017	2,36		Algorithm converged.	1,23	4,51	0,0094		0,42		Algorithm converged.	0,22	0,81
	DECREASED APPETITE	n/a	1783	100,0	6	0,3	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEHYDRATION	n/a	1783	100,0	11	0,6	1822	100,0	3	0,2	3,76		Algorithm converged.	1,05	13,51	0,005		Algorithm converged.	0,000	0,009	3,75		Algorithm converged.	1,05	13,41	0,0423		0,27		Algorithm converged.	0,07	0,96
	DIABETES MELLITUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ELECTROLYTE IMBALANCE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FLUID RETENTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	HYPERKALAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOGLYCAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	n/a	1783	100,0	6	0,3	1822	100,0	2	0,1	3,07		Algorithm converged.	0,62	15,24	0,002		Algorithm converged.	-0,001	0,005	3,07		Algorithm converged.	0,62	15,17	0,1697		0,33		Algorithm converged.	0,07	1,61

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOMAGNESAEMIA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPONATRAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOVOLAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TUMOUR LYSIS SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4	0,73		Algorithm converged.	0,23	2,30	-0,001		Algorithm converged.	-0,005	0,003	0,73		Algorithm converged.	0,23	2,30	0,5902		1,37		Algorithm converged.	0,44	4,31
	ARTHRALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACK PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERVERTEBRAL DISC PROTRUSION	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	MUSCULOSKELETAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PAIN IN EXTREMITY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ROTATOR CUFF SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SJOGREN'S SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	8	0,4	1822	100,0	16	0,9	0,51		Algorithm converged.	0,22	1,19	-0,004		Algorithm converged.	-0,010	0,001	0,51		Algorithm converged.	0,22	1,19	0,1199		1,96		Algorithm converged.	0,84	4,56
	ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ADENOCARCINOMA PANCREAS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BENIGN BREAST NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GASTRIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRADUCTAL PROLIFERATIVE BREAST LESION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MALIGNANT MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA IN SITU	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONOCLONAL GAMMOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELODYSPLASTIC SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURILEMMOMA BENIGN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PAPILLARY THYROID CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARATHYROID TUMOUR BENIGN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PELVIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SMALL CELL LUNG CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SQUAMOUS CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE LEIOMYOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	25	1,4	1822	100,0	16	0,9	1,61		Algorithm converged.	0,85	3,02	0,005		Algorithm converged.	-0,002	0,012		1,60		Algorithm converged.	0,86	2,98	0,1417		0,63		Algorithm converged.	0,34	1,17

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATAXIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	DIZZINESS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHAGE INTRACRANIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEAD TITUBATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEADACHE	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTERCOSTAL NEURALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOSS OF CONSCIOUSNESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUROPATHY PERIPHERAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARAESTHESIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOGENIC SEIZURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEIZURE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002	2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	n/a	1783	100,0	10	0,6	1822	100,0	4	0,2	2,56		Algorithm converged.	0,80	8,19	0,003		Algorithm converged.	-0,001	0,007	2,55		Algorithm converged.	0,80	8,13	0,1123		0,39		Algorithm converged.	0,12	1,25

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THALAMIC INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRANSIENT ISCHAEMIC ATTACK	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	TRIGEMINAL NEURALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PRODUCT ISSUE	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562021 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE EXTRUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	8	0,4	1822	100,0	7	0,4	1,17		Algorithm converged.	0,42	3,23	0,001		Algorithm converged.	-0,004	0,005	1,17		Algorithm converged.	0,42	3,21	0,7638		0,86		Algorithm converged.	0,31	2,36
	ANXIETY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	MAJOR DEPRESSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MENTAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERSISTENT DEPRESSIVE DISORDER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERSONALITY CHANGE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PSYCHOTIC DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	REACTIVE PSYCHOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUICIDAL IDEATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDE ATTEMPT	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	6	0,3	1822	100,0	8	0,4	0,77		Algorithm converged.	0,27	2,21	-0,001		Algorithm converged.	-0,005	0,003	0,77		Algorithm converged.	0,27	2,20	0,6216		1,30		Algorithm converged.	0,45	3,75
	ACUTE KIDNEY INJURY	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1	2,05		Algorithm converged.	0,37	11,18	0,001		Algorithm converged.	-0,002	0,004	2,04		Algorithm converged.	0,37	11,14	0,4088		0,49		Algorithm converged.	0,09	2,67
	DYSURIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL COLIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	RENAL IMPAIRMENT	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URETERIC OBSTRUCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY INCONTINENCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY RETENTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3	0,82		Algorithm converged.	0,22	3,05	-0,001		Algorithm converged.	-0,004	0,003	0,82		Algorithm converged.	0,22	3,04	0,7636		1,22		Algorithm converged.	0,33	4,55
	BREAST INFLAMMATION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	CERVICAL POLYP	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEAVY MENSTRUAL BLEEDING	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OVARIAN CYST	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PELVIC CYST	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VAGINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	20	1,1	1822	100,0	26	1,4	0,78		Algorithm converged.	0,44	1,41	-0,003		Algorithm converged.	-0,010	0,004	0,79		Algorithm converged.	0,44	1,40	0,4154		1,27		Algorithm converged.	0,71	2,27
	ASTHMA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATELECTASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRONCHIECTASIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHOSPASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COUGH	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	DYSPHONIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPNOEA	n/a	1783	100,0	3	0,2	1822	100,0	7	0,4	0,44		Algorithm converged.	0,11	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,44		Algorithm converged.	0,11	1,69	0,2310		2,28		Algorithm converged.	0,59	8,82
	DYSPNOEA EXERTIONAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EPISTAXIS	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	INTERSTITIAL LUNG DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG CONSOLIDATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509652 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LUNG INFILTRATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL POLYPS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PLEURAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMONITIS	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2	0,68		Algorithm converged.	0,11	4,08	-0,001		Algorithm converged.	-0,003	0,002	0,68		Algorithm converged.	0,11	4,07	0,6739		1,47		Algorithm converged.	0,25	8,77
	PNEUMOTHORAX	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1	0,51		Algorithm converged.	0,05	5,64	-0,001		Algorithm converged.	-0,002	0,001	0,51		Algorithm converged.	0,05	5,63	0,5834		1,96		Algorithm converged.	0,18	21,57
	PULMONARY EMBOLISM	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1	1,02		Algorithm converged.	0,14	7,26	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,14	7,25	0,9827		0,98		Algorithm converged.	0,14	6,94
	PULMONARY FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	10	0,6	1822	100,0	4	0,2	2,56		Algorithm converged.	0,80	8,19	0,003		Algorithm converged.	-0,001	0,007	2,55		Algorithm converged.	0,80	8,13	0,1123		0,39		Algorithm converged.	0,12	1,25

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DERMATITIS ACNEIFORM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS EXFOLIATIVE GENERALISED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RASH	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1	3,07		Algorithm converged.	0,32	29,53	0,001		Algorithm converged.	-0,001	0,003	3,07		Algorithm converged.	0,32	29,44	0,3318		0,33		Algorithm converged.	0,03	3,13
	RASH MACULAR	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SKIN ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXIC SKIN ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URTICARIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378508965 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
SURGICAL AND MEDICAL PROCEDURE	-Total	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.09018451 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST TUMOUR EXCISION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HOSPITALISATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
VASCULAR DISORDER	-Total	n/a	1783	100,0	16	0,9	1822	100,0	19	1,0	0,86		Algorithm converged.	0,44	1,68	-0,001		Algorithm converged.	-0,008	0,005	0,86		Algorithm converged.	0,44	1,67	0,6564		1,16		Algorithm converged.	0,60	2,25
	AXILLARY VEIN THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEEP VEIN THROMBOSIS	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1	2,04		Algorithm converged.	0,19	22,57	0,001		Algorithm converged.	-0,001	0,002		2,04		Algorithm converged.	0,19	22,52	0,5593		0,49		Algorithm converged.	0,04	5,39
	EMBOLISM	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1	1,53		Algorithm converged.	0,26	9,19	0,001		Algorithm converged.	-0,002	0,003		1,53		Algorithm converged.	0,26	9,16	0,6397		0,65		Algorithm converged.	0,11	3,90
	EMBOLISM VENOUS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 209.58186164 is greater than the limit of 0.0001. The convergence is questionable.	-0,047	0,046	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPERTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2	0,26		Algorithm converged.	0,03	2,28	-0,002		Algorithm converged.	-0,004	0,001	0,26		Algorithm converged.	0,03	2,28	0,2220		3,91		Algorithm converged.	0,44	34,99
	HYPOTENSION	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2	0,51		Algorithm converged.	0,09	2,79	-0,001		Algorithm converged.	-0,004	0,002	0,51		Algorithm converged.	0,09	2,79	0,4378		1,96		Algorithm converged.	0,36	10,67
	LYMPHOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	PHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCLAVIAN VEIN THROMBOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509423 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THROMBOPHLEBITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1	1,02		Algorithm converged.	0,06	16,35	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,32	0,9878		0,98		Algorithm converged.	0,06	15,63
	THROMBOSIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 80.225830277 is greater than the limit of 0.0001. The convergence is questionable.	-0,048	0,045	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VARICOSE VEIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,014	*	WARNING: The relative Hessian convergence criterion of 76.378509194 is greater than the limit of 0.0001. The convergence is questionable.	-0,038	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VENOUS THROMBOSIS LIMB	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0	NE		Algorithm converged.	NE	NE	0,018	*	WARNING: The relative Hessian convergence criterion of 54.170562527 is greater than the limit of 0.0001. The convergence is questionable.	-0,033	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AESAE_S1.xls

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
05MAY2022 18:34																															

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	162	10,4	1601	87,9	145	9,1	1,16		Algorithm converged.	0,92	1,47	0,013		Algorithm converged.	-0,008	0,034	1,14		Algorithm converged.	0,92	1,42	0,2166	0,0731	0,87		Algorithm converged.	0,71	1,08
		>= 65	219	12,3	30	13,7	221	12,1	41	18,6	0,70		Algorithm converged.	0,42	1,16	-0,049		Algorithm converged.	-0,117	0,020	0,74		Algorithm converged.	0,48	1,14	0,1691		1,35		Algorithm converged.	0,88	2,09
	ANAEMIA	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	3	1,4	221	12,1	5	2,3	0,60		Algorithm converged.	0,14	2,54	-0,009		Algorithm converged.	-0,034	0,016	0,61		Algorithm converged.	0,15	2,50	0,4883		1,65		Algorithm converged.	0,40	6,83
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	7	0,4	1601	87,9	5	0,3	1,44		Algorithm converged.	0,45	4,53	0,001		Algorithm converged.	-0,003	0,006	1,43		Algorithm converged.	0,46	4,51	0,5381	-	0,70		Algorithm converged.	0,22	2,19
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FEBRILE NEUTROPENIA	< 65	1564	87,7	127	8,1	1601	87,9	118	7,4	1,11		Algorithm converged.	0,86	1,44	0,007		Algorithm converged.	-0,011	0,026	1,10		Algorithm converged.	0,87	1,40	0,4302	0,9700	0,91		Algorithm converged.	0,71	1,15
		>= 65	219	12,3	27	12,3	221	12,1	25	11,3	1,10		Algorithm converged.	0,62	1,97	0,010		Algorithm converged.	-0,050	0,070	1,09		Algorithm converged.	0,65	1,82	0,7413		0,92		Algorithm converged.	0,55	1,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOLYTIC ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOPENIA	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHADENOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	< 65	1564	87,7	17	1,1	1601	87,9	15	0,9	1,16		Algorithm converged.	0,58	2,33	0,002		Algorithm converged.	-0,005	0,008	1,16		Algorithm converged.	0,58	2,31	0,6734	-	0,86		Algorithm converged.	0,43	1,72
		>= 65	219	12,3	1	0,5	221	12,1	6	2,7	0,16		Algorithm converged.	0,02	1,38	-0,023		Algorithm converged.	-0,046	0,001	0,17		Algorithm converged.	0,02	1,39	0,0975		5,95		Algorithm converged.	0,72	48,98

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
CARDIAC DISORDER	-Total	< 65	1564	87,7	26	1,7	1601	87,9	21	1,3	1,27		Algorithm converged.	0,71	2,27	0,004		Algorithm converged.	-0,005	0,012	1,27		Algorithm converged.	0,72	2,24	0,4159	0,9931	0,79		Algorithm converged.	0,45	1,40
		>= 65	219	12,3	10	4,6	221	12,1	8	3,6	1,27		Algorithm converged.	0,49	3,29	0,009		Algorithm converged.	-0,028	0,046	1,26		Algorithm converged.	0,51	3,14	0,6172		0,79		Algorithm converged.	0,32	1,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ACUTE CORONARY SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANGINA PECTORIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ATRIAL FIBRILLATION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ATRIAL THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRADYCARDIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	< 65	1564	87,7	16	1,0	1601	87,9	9	0,6	1,83		Algorithm converged.	0,81	4,15	0,005		Algorithm converged.	-0,002	0,011	1,82		Algorithm converged.	0,81	4,11	0,1492	0,7587	0,55		Algorithm converged.	0,24	1,24
		>= 65	219	12,3	9	4,1	221	12,1	4	1,8	2,32		Algorithm converged.	0,71	7,67	0,023		Algorithm converged.	-0,009	0,055	2,27		Algorithm converged.	0,71	7,26	0,1669		0,44		Algorithm converged.	0,14	1,41
	CARDIAC FAILURE CONGESTIVE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EXTRASYSTOLES	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METABOLIC CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013		1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	PALPITATIONS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PERICARDIAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SINUS NODE DYSFUNCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STRESS CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA PAROXYSMAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENTRICULAR ARRHYTHMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	APLASIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
EAR AND LABYRINTH DISORDER	-Total	< 65	1564	87,7	3	0,2	1601	87,9	4	0,2	0,77		Algorithm converged.	0,17	3,43	-0,001		Algorithm converged.	-0,004	0,003	0,77		Algorithm converged.	0,17	3,42	0,7290	-	1,30		Algorithm converged.	0,29	5,81

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXTERNAL EAR INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TYMPANIC MEMBRANE PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VESTIBULAR DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GOITRE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE	
	THYROID DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	62	4,0	1601	87,9	45	2,8	1,43		Algorithm converged.	0,97	2,11	0,012		Algorithm converged.	-0,001	0,024	1,41		Algorithm converged.	0,97	2,06	0,0742	0,2588	0,71		Algorithm converged.	0,49	1,03	
		>= 65	219	12,3	24	11,0	221	12,1	11	5,0	2,35		Algorithm converged.	1,12	4,92	0,060		Algorithm converged.	0,009	0,110	2,20		Algorithm converged.	1,11	4,38	0,0247		0,45		Algorithm converged.	0,23	0,90	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL PAIN	< 65	1564	87,7	4	0,3	1601	87,9	3	0,2	1,37		Algorithm converged.	0,31	6,11	0,001		Algorithm converged.	-0,003	0,004	1,36		Algorithm converged.	0,31	6,09	0,6835	-	0,73		Algorithm converged.	0,16	3,27
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ABDOMINAL PAIN UPPER	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	CONSTIPATION	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA	< 65	1564	87,7	29	1,9	1601	87,9	11	0,7	2,73		Algorithm converged.	1,36	5,49	0,012		Algorithm converged.	0,004	0,019	2,70		Algorithm converged.	1,35	5,38	0,0048	0,5727	0,37		Algorithm converged.	0,19	0,74
		>= 65	219	12,3	12	5,5	221	12,1	3	1,4	4,21		Algorithm converged.	1,17	15,14	0,041		Algorithm converged.	0,007	0,075	4,04		Algorithm converged.	1,16	14,11	0,0288		0,25		Algorithm converged.	0,07	0,87

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DUODENAL ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTERITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ENTEROCOLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRIC ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTRITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROINTESTINAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROOESOPHAGEAL REFLUX DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	ILEUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	INGUINAL HERNIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAUSEA	< 65	1564	87,7	9	0,6	1601	87,9	7	0,4	1,32		Algorithm converged.	0,49	3,55	0,001		Algorithm converged.	-0,004	0,006	1,32		Algorithm converged.	0,49	3,53	0,5848	-	0,76		Algorithm converged.	0,28	2,04
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4	0,33		Algorithm converged.	0,03	3,23	-0,009		Algorithm converged.	-0,027	0,009	0,34		Algorithm converged.	0,04	3,21	0,3437		2,97		Algorithm converged.	0,31	28,36

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OEDEMA MOUTH	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCREATITIS	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	STOMATITIS	< 65	1564	87,7	5	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	SUBILEUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VOMITING	< 65	1564	87,7	9	0,6	1601	87,9	9	0,6	1,02		Algorithm converged.	0,41	2,59	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,41	2,57	0,9603	-	0,98		Algorithm converged.	0,39	2,45
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	34	2,2	1601	87,9	46	2,9	0,75		Algorithm converged.	0,48	1,18	-0,007		Algorithm converged.	-0,018	0,004	0,76		Algorithm converged.	0,49	1,17	0,2118	0,2279	1,32		Algorithm converged.	0,85	2,05
		>= 65	219	12,3	11	5,0	221	12,1	8	3,6	1,41		Algorithm converged.	0,56	3,57	0,014		Algorithm converged.	-0,024	0,052	1,39		Algorithm converged.	0,57	3,38	0,4714		0,72		Algorithm converged.	0,30	1,76

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASTHENIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	CHEST PAIN	< 65	1564	87,7	3	0,2	1601	87,9	6	0,4	0,51		Algorithm converged.	0,13	2,05	-0,002		Algorithm converged.	-0,006	0,002	0,51		Algorithm converged.	0,13	2,04	0,3429	-	1,95		Algorithm converged.	0,49	7,80
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHILLS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEVICE RELATED THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	FATIGUE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFLUENZA LIKE ILLNESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MASS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUCOSAL INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NON-CARDIAC CHEST PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PYREXIA	< 65	1564	87,7	23	1,5	1601	87,9	34	2,1	0,69		Algorithm converged.	0,40	1,17	-0,007		Algorithm converged.	-0,016	0,003	0,69		Algorithm converged.	0,41	1,17	0,1697	-	1,44		Algorithm converged.	0,85	2,44
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4	1,01		Algorithm converged.	0,20	5,06	0,000		Algorithm converged.	-0,022	0,022	1,01		Algorithm converged.	0,21	4,95	0,9911		0,99		Algorithm converged.	0,20	4,86
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BILIARY COLIC	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLANGITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEPATIC FUNCTION ABNORMAL	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	11	0,7	1601	87,9	7	0,4	1,61		Algorithm converged.	0,62	4,17	0,003		Algorithm converged.	-0,003	0,008	1,61		Algorithm converged.	0,63	4,14	0,3242	-	0,62		Algorithm converged.	0,24	1,60
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	ANAPHYLACTIC REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615522 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERSENSITIVITY	< 65	1564	87,7	6	0,4	1601	87,9	2	0,1	3,08		Algorithm converged.	0,62	15,28	0,003		Algorithm converged.	-0,001	0,006	3,07		Algorithm converged.	0,62	15,19	0,1690	-	0,33		Algorithm converged.	0,07	1,61
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	101	6,5	1601	87,9	94	5,9	1,11		Algorithm converged.	0,83	1,48	0,006		Algorithm converged.	-0,011	0,023	1,10		Algorithm converged.	0,84	1,44	0,4929	0,4540	0,91		Algorithm converged.	0,69	1,19
		>= 65	219	12,3	25	11,4	221	12,1	18	8,1	1,45		Algorithm converged.	0,77	2,75	0,033		Algorithm converged.	-0,023	0,088	1,40		Algorithm converged.	0,79	2,49	0,2509		0,71		Algorithm converged.	0,40	1,27
	ABDOMINAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABSCESS ORAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563192 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	APPENDICITIS PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BACTERIAL INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST CELLULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHITIS	< 65	1564	87,7	4	0,3	1601	87,9	1	<0.1	4,10		Algorithm converged.	0,46	36,75	0,002		Algorithm converged.	-0,001	0,005	4,09		Algorithm converged.	0,46	36,59	0,2071	-	0,24		Algorithm converged.	0,03	2,18

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL									
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE									
	CELLULITIS	< 65	1564	87,7	10	0,6	1601	87,9	12	0,7	0,85		Algorithm converged.	0,37	1,98	-0,001		Algorithm converged.	-0,007	0,005	0,85		Algorithm converged.	0,37	1,97	0,7095	-	1,17		Algorithm converged.	0,51	2,71									
		>= 65	219	12,3	4	1,8	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE									
	CHRONIC SINUSITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE									
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE									

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CLOSTRIDIUM DIFFICILE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIARRHOEA INFECTIOUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIVERTICULITIS	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1	1,54		Algorithm converged.	0,26	9,21	0,001		Algorithm converged.	-0,002	0,003	1,54		Algorithm converged.	0,26	9,18	0,6383	-	0,65		Algorithm converged.	0,11	3,89
		>= 65	219	12,3	0	0,0	221	12,1	4	1,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS INTESTINAL PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROENTERITIS	< 65	1564	87,7	6	0,4	1601	87,9	1	<0.1	6,16		Algorithm converged.	0,74	51,24	0,003		Algorithm converged.	0,000	0,007	6,14		Algorithm converged.	0,74	50,96	0,0927	-	0,16		Algorithm converged.	0,02	1,35

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROENTERITIS VIRAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES ZOSTER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INFECTED SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOCALISED INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LOWER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHANGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MASTITIS	< 65	1564	87,7	3	0,2	1601	87,9	3	0,2	1,02		Algorithm converged.	0,21	5,08	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,21	5,06	0,9771	-	0,98		Algorithm converged.	0,20	4,83
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUTROPENIC INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA ACUTE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARONYCHIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	1,0000			>999		Algorithm converged.	0,00	NE	
	PERITONSILLAR ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	PHLEBITIS INFECTIVE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
	PLEURAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	< 65	1564	87,7	12	0,8	1601	87,9	18	1,1	0,68		Algorithm converged.	0,33	1,42	-0,004		Algorithm converged.	-0,010	0,003	0,68		Algorithm converged.	0,33	1,41	0,3030	-	1,47		Algorithm converged.	0,71	3,03
		>= 65	219	12,3	4	1,8	221	12,1	3	1,4	1,35		Algorithm converged.	0,30	6,11	0,005		Algorithm converged.	-0,019	0,028	1,35		Algorithm converged.	0,30	5,94	0,6953		0,74		Algorithm converged.	0,17	3,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA ASPIRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMONIA PNEUMOCOCCAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE WOUND INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PYELONEPHRITIS ACUTE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RESPIRATORY TRACT INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	SEPSIS	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4	0,34		Algorithm converged.	0,07	1,69	-0,002		Algorithm converged.	-0,006	0,001	0,34		Algorithm converged.	0,07	1,69	0,1875	-	2,93		Algorithm converged.	0,59	14,50
		>= 65	219	12,3	3	1,4	221	12,1	2	0,9	1,52		Algorithm converged.	0,25	9,19	0,005		Algorithm converged.	-0,015	0,024	1,51		Algorithm converged.	0,26	8,97	0,6479		0,66		Algorithm converged.	0,11	3,92
	SEPTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SERRATIA INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.834276541 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	SOFT TISSUE INFECTION	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615388 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STAPHYLOCOCCAL SKIN INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUBCUTANEOUS ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TONSILLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOOTH INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	4	0,2	1,28		Algorithm converged.	0,34	4,78	0,001		Algorithm converged.	-0,003	0,004	1,28		Algorithm converged.	0,34	4,76	0,7129	-	0,78		Algorithm converged.	0,21	2,90
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VARICELLA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VIRAL INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	20	1,3	1601	87,9	16	1,0	1,28		Algorithm converged.	0,66	2,49	0,003		Algorithm converged.	-0,005	0,010	1,28		Algorithm converged.	0,67	2,46	0,4598	-	0,78		Algorithm converged.	0,41	1,50
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9	2,04		Algorithm converged.	0,37	11,24	0,009		Algorithm converged.	-0,012	0,031	2,02		Algorithm converged.	0,37	10,91	0,4146		0,50		Algorithm converged.	0,09	2,68
	ACCIDENTAL OVERDOSE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AVULSION FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST PROCEDURAL COMPLICATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONCUSSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FALL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FEMORAL NECK FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FRACTURED SACRUM	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	GRAFT THROMBOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HUMERUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ILIUM FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED REACTION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTENTIONAL OVERDOSE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOWER LIMB FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PNEUMOTHORAX TRAUMATIC	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY RADIATION INJURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIUS FRACTURE	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,021	*	WARNING: The relative Hessian convergence criterion of 41.466615254 is greater than the limit of 0.0001. The convergence is questionable.	-0,032	0,074	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ROAD TRAFFIC ACCIDENT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN LACERATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THERMAL BURN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TIBIA FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	TOXICITY TO VARIOUS AGENTS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WRIST FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	< 65	1564	87,7	17	1,1	1601	87,9	11	0,7	1,59		Algorithm converged.	0,74	3,40	0,004		Algorithm converged.	-0,003	0,011	1,58		Algorithm converged.	0,74	3,37	0,2339	-	0,63		Algorithm converged.	0,30	1,35
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD CREATININE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BLOOD GLUCOSE FLUCTUATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	EJECTION FRACTION DECREASED	< 65	1564	87,7	7	0,4	1601	87,9	4	0,2	1,79		Algorithm converged.	0,52	6,14	0,002		Algorithm converged.	-0,002	0,006	1,79		Algorithm converged.	0,53	6,11	0,3515	-	0,56		Algorithm converged.	0,16	1,90
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOGLOBIN DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PLATELET COUNT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TROPONIN INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	19	1,2	1601	87,9	7	0,4	2,80		Algorithm converged.	1,17	6,68	0,008		Algorithm converged.	0,001	0,014	2,78		Algorithm converged.	1,17	6,59	0,0204	0,5419	0,36		Algorithm converged.	0,15	0,85
		>= 65	219	12,3	11	5,0	221	12,1	6	2,7	1,90		Algorithm converged.	0,69	5,22	0,023		Algorithm converged.	-0,013	0,059	1,85		Algorithm converged.	0,70	4,91	0,2171		0,54		Algorithm converged.	0,20	1,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DECREASED APPETITE	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,023	*	WARNING: The relative Hessian convergence criterion of 35.734963577 is greater than the limit of 0.0001. The convergence is questionable.	-0,030	0,075	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEHYDRATION	< 65	1564	87,7	7	0,4	1601	87,9	3	0,2	2,39		Algorithm converged.	0,62	9,28	0,003		Algorithm converged.	-0,001	0,007	2,39		Algorithm converged.	0,62	9,22	0,2064	-	0,42		Algorithm converged.	0,11	1,62

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	4	1,8	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIABETES MELLITUS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ELECTROLYTE IMBALANCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	FLUID RETENTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	HYPERGLYCAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9	0,50		Algorithm converged.	0,05	5,58	-0,004		Algorithm converged.	-0,020	0,011	0,50		Algorithm converged.	0,05	5,52	0,5753		1,98		Algorithm converged.	0,18	21,70
	HYPERKALAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPOCALCAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOGLYCAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1	2,05		Algorithm converged.	0,37	11,21	0,001		Algorithm converged.	-0,002	0,004	2,05		Algorithm converged.	0,38	11,16	0,4076	-	0,49		Algorithm converged.	0,09	2,66
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOMAGNESAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPONATRAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	TUMOUR LYSIS SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	6	0,4	0,68		Algorithm converged.	0,19	2,42	-0,001		Algorithm converged.	-0,005	0,003	0,68		Algorithm converged.	0,19	2,41	0,5533	-	1,47		Algorithm converged.	0,41	5,18
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ARTHRALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACK PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERVERTEBRAL DISC PROTRUSION	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MUSCULOSKELETAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	MYALGIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PAIN IN EXTREMITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROTATOR CUFF SYNDROME	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SJOGREN'S SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	7	0,4	1601	87,9	11	0,7	0,65		Algorithm converged.	0,25	1,68	-0,002		Algorithm converged.	-0,008	0,003		0,65		Algorithm converged.	0,25	1,68	0,3741	-		1,54		Algorithm converged.	0,60	3,95
		>= 65	219	12,3	1	0,5	221	12,1	5	2,3	0,20		Algorithm converged.	0,02	1,71	-0,018		Algorithm converged.	-0,040	0,003		0,20		Algorithm converged.	0,02	1,71	0,1425			4,95		Algorithm converged.	0,58	42,07
	ACUTE MYELOID LEUKAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002		1,02		Algorithm converged.	0,06	16,35	0,9868	-		0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ADENOCARCINOMA PANCREAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BENIGN BREAST NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTRADUCTAL PROLIFERATIVE BREAST LESION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LENTIGO MALIGNA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MALIGNANT MELANOMA IN SITU	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MENINGIOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MONOCLONAL GAMMOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELODYSPLASTIC SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEURILEMMOMA BENIGN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLARY THYROID CANCER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARATHYROID TUMOUR BENIGN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	SQUAMOUS CELL CARCINOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	13	0,8	1601	87,9	11	0,7	1,21		Algorithm converged.	0,54	2,71	0,001		Algorithm converged.	-0,005	0,007	1,21		Algorithm converged.	0,54	2,69	0,6408	0,2886	0,83		Algorithm converged.	0,37	1,84
		>= 65	219	12,3	12	5,5	221	12,1	5	2,3	2,50		Algorithm converged.	0,87	7,23	0,032		Algorithm converged.	-0,004	0,068	2,42		Algorithm converged.	0,87	6,76	0,0912		0,41		Algorithm converged.	0,15	1,15
	ATAXIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIZZINESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMORRHAGE INTRACRANIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAD TITUBATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEADACHE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTERCOSTAL NEURALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	LOSS OF CONSCIOUSNESS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUROPATHY PERIPHERAL	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NEUROTOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOGENIC SEIZURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEIZURE	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SYNCOPE	< 65	1564	87,7	5	0,3	1601	87,9	3	0,2	1,71		Algorithm converged.	0,41	7,16	0,001		Algorithm converged.	-0,002	0,005	1,71		Algorithm converged.	0,41	7,13	0,4639	-	0,59		Algorithm converged.	0,14	2,45
		>= 65	219	12,3	5	2,3	221	12,1	1	0,5	5,14		Algorithm converged.	0,60	44,36	0,018		Algorithm converged.	-0,003	0,040	5,05		Algorithm converged.	0,59	42,84	0,1380		0,20		Algorithm converged.	0,02	1,68
	THALAMIC INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSIENT ISCHAEMIC ATTACK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRIGEMINAL NEURALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PRODUCT ISSUE	-Total	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,019	*	WARNING: The relative Hessian convergence criterion of 50.8342767 is greater than the limit of 0.0001. The convergence is questionable.	-0,035	0,073	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	DEVICE DISLOCATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	DEVICE EXTRUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	6	0,4	0,85		Algorithm converged.	0,26	2,80	-0,001		Algorithm converged.	-0,005	0,004	0,85		Algorithm converged.	0,26	2,79	0,7926	-	1,17		Algorithm converged.	0,36	3,83	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15
	ANXIETY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEPRESSION	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MAJOR DEPRESSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PERSISTENT DEPRESSIVE DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSONALITY CHANGE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSYCHOTIC DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	REACTIVE PSYCHOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SUICIDAL IDEATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8	0,50		Algorithm converged.	0,09	2,76	-0,009		Algorithm converged.	-0,031	0,013	0,50		Algorithm converged.	0,09	2,73	0,4268		1,98		Algorithm converged.	0,37	10,71
	ACUTE KIDNEY INJURY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9	1,01		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,018	0,018	1,01		Algorithm converged.	0,14	7,10	0,9927		0,99		Algorithm converged.	0,14	6,97
	DYSURIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL FAILURE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RENAL IMPAIRMENT	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URETERIC OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY INCONTINENCE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URINARY RETENTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	< 65	1564	87,7	4	0,3	1601	87,9	4	0,2	1,02		Algorithm converged.	0,26	4,10	0,000		Algorithm converged.	-0,003	0,004	1,02		Algorithm converged.	0,26	4,09	0,9736	-	0,98		Algorithm converged.	0,24	3,90

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BREAST PAIN	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL POLYP	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEAVY MENSTRUAL BLEEDING	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OVARIAN CYST	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PELVIC CYST	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	17	1,1	1601	87,9	19	1,2	0,91		Algorithm converged.	0,47	1,77	-0,001		Algorithm converged.	-0,008	0,006	0,92		Algorithm converged.	0,48	1,76	0,7913	0,3100	1,09		Algorithm converged.	0,57	2,09

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	3	1,4	221	12,1	7	3,2	0,42		Algorithm converged.	0,11	1,66	-0,018		Algorithm converged.	-0,046	0,010	0,43		Algorithm converged.	0,11	1,65	0,2200		2,31		Algorithm converged.	0,61	8,83
	ASTHMA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHIECTASIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COUGH	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DYSPHONIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	< 65	1564	87,7	3	0,2	1601	87,9	5	0,3	0,61		Algorithm converged.	0,15	2,57	-0,001		Algorithm converged.	-0,005	0,002	0,61		Algorithm converged.	0,15	2,57	0,5040	-	1,63		Algorithm converged.	0,39	6,80
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSPNOEA EXERTIONAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	EPISTAXIS	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERSTITIAL LUNG DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1	0,51		Algorithm converged.	0,05	5,65	-0,001		Algorithm converged.	-0,003	0,002	0,51		Algorithm converged.	0,05	5,64	0,5843	-	1,95		Algorithm converged.	0,18	21,52
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG INFILTRATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658564057 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASAL POLYPS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1	1,02		Algorithm converged.	0,14	7,28	0,000		Algorithm converged.	-0,002	0,003	1,02		Algorithm converged.	0,14	7,26	0,9813	-	0,98		Algorithm converged.	0,14	6,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 101.76181105 is greater than the limit of 0.0001. The convergence is questionable.	-0,051	0,048	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PULMONARY EMBOLISM	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	8	0,5	1601	87,9	3	0,2	2,74		Algorithm converged.	0,73	10,34	0,003		Algorithm converged.	-0,001	0,007	2,73		Algorithm converged.	0,73	10,27	0,1374	-	0,37		Algorithm converged.	0,10	1,38
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5	2,03		Algorithm converged.	0,18	22,53	0,005		Algorithm converged.	-0,011	0,020	2,02		Algorithm converged.	0,18	22,10	0,5652		0,50		Algorithm converged.	0,05	5,42
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ACNEIFORM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	RASH	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH MACULAR	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SKIN ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563841 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXIC SKIN ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URTICARIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563408 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SURGICAL AND MEDICAL PROCEDURE	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE
	BREAST TUMOUR EXCISION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HOSPITALISATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
VASCULAR DISORDER	-Total	< 65	1564	87,7	10	0,6	1601	87,9	16	1,0	0,64		Algorithm converged.	0,29	1,41	-0,004		Algorithm converged.	-0,010	0,003		0,64		Algorithm converged.	0,29	1,41	0,2660	-		1,56		Algorithm converged.	0,71	3,43
		>= 65	219	12,3	6	2,7	221	12,1	3	1,4	2,05		Algorithm converged.	0,51	8,29	0,014		Algorithm converged.	-0,013	0,040		2,02		Algorithm converged.	0,51	7,97	0,3162			0,50		Algorithm converged.	0,13	1,96

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AXILLARY VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1	2,05		Algorithm converged.	0,19	22,62	0,001		Algorithm converged.	-0,001	0,003	2,05		Algorithm converged.	0,19	22,56	0,5584	-	0,49		Algorithm converged.	0,04	5,38
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1	3,07		Algorithm converged.	0,32	29,59	0,001		Algorithm converged.	-0,001	0,004	3,07		Algorithm converged.	0,32	29,49	0,3310	-	0,33		Algorithm converged.	0,03	3,13
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	1,0000		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EMBOLISM VENOUS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPERTENSION	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	HYPOTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2	0,34		Algorithm converged.	0,04	3,28	-0,001		Algorithm converged.	-0,004	0,001	0,34		Algorithm converged.	0,04	3,28	0,3515	-	2,93		Algorithm converged.	0,31	28,14
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74
	LYMPHOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 186.67780876 is greater than the limit of 0.0001. The convergence is questionable.	-0,050	0,049	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THROMBOPHLEBITIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1	1,02		Algorithm converged.	0,06	16,38	0,000		Algorithm converged.	-0,002	0,002	1,02		Algorithm converged.	0,06	16,35	0,9868	-	0,98		Algorithm converged.	0,06	15,60
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	< 65	1564	87,7	0	0,0	1601	87,9	3	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VARICOSE VEIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENOUS THROMBOSIS LIMB	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0	NE		Algorithm converged.	NE	NE	0,015	*	WARNING: The relative Hessian convergence criterion of 71.658563625 is greater than the limit of 0.0001. The convergence is questionable.	-0,040	0,070	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AESAE_S1.xls
05MAY2022 18:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	21	8,0	252	13,8	24	9,5	0,83		Algorithm converged.	0,45	1,53	-0,015		Algorithm converged.	-0,064	0,034	0,84		Algorithm converged.	0,48	1,47	0,5458	-	1,19		Algorithm converged.	0,68	2,08
		Western Europe	814	45,7	87	10,7	824	45,2	93	11,3	0,94		Algorithm converged.	0,69	1,28	-0,006		Algorithm converged.	-0,036	0,024	0,95		Algorithm converged.	0,72	1,25	0,6987		1,06		Algorithm converged.	0,80	1,39
		Asia Pacific	482	27,0	65	13,5	517	28,4	58	11,2	1,23		Algorithm converged.	0,85	1,80	0,023		Algorithm converged.	-0,018	0,064	1,20		Algorithm converged.	0,86	1,67	0,2766		0,83		Algorithm converged.	0,60	1,16
		Latin America	42	2,4	5	11,9	45	2,5	2	4,4	2,91		Algorithm converged.	0,53	15,87	0,075		Algorithm converged.	-0,040	0,190	2,68		Algorithm converged.	0,55	13,07	0,2231		0,37		Algorithm converged.	0,08	1,82
		Other	183	10,3	14	7,7	184	10,1	9	4,9	1,61		Algorithm converged.	0,68	3,82	0,028		Algorithm converged.	-0,022	0,077	1,56		Algorithm converged.	0,69	3,52	0,2803		0,64		Algorithm converged.	0,28	1,44
	ANAEMIA	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2	3,23		Algorithm converged.	0,34	31,17	0,004		Algorithm converged.	-0,004	0,012	3,22		Algorithm converged.	0,34	30,83	0,3107		0,31		Algorithm converged.	0,03	2,98
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	17	6,5	252	13,8	18	7,1	0,90		Algorithm converged.	0,45	1,79	-0,007		Algorithm converged.	-0,050	0,037	0,91		Algorithm converged.	0,48	1,72	0,7686	-	1,10		Algorithm converged.	0,58	2,09
		Western Europe	814	45,7	66	8,1	824	45,2	72	8,7	0,92		Algorithm converged.	0,65	1,31	-0,006		Algorithm converged.	-0,033	0,021	0,93		Algorithm converged.	0,67	1,28	0,6465		1,08		Algorithm converged.	0,78	1,48
		Asia Pacific	482	27,0	55	11,4	517	28,4	45	8,7	1,35		Algorithm converged.	0,89	2,05	0,027		Algorithm converged.	-0,010	0,064	1,31		Algorithm converged.	0,90	1,91	0,1558		0,76		Algorithm converged.	0,52	1,11
		Latin America	42	2,4	5	11,9	45	2,5	2	4,4	2,91		Algorithm converged.	0,53	15,87	0,075		Algorithm converged.	-0,040	0,190	2,68		Algorithm converged.	0,55	13,07	0,2231		0,37		Algorithm converged.	0,08	1,82
		Other	183	10,3	11	6,0	184	10,1	6	3,3	1,90		Algorithm converged.	0,69	5,24	0,028		Algorithm converged.	-0,015	0,070	1,84		Algorithm converged.	0,70	4,88	0,2182		0,54		Algorithm converged.	0,20	1,44
	HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LEUKOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4	0,67		Algorithm converged.	0,11	4,04	-0,001		Algorithm converged.	-0,007	0,004	0,67		Algorithm converged.	0,11	4,03	0,6662		1,48		Algorithm converged.	0,25	8,84
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHADENOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	9	1,1	824	45,2	10	1,2	0,91		Algorithm converged.	0,37	2,25	-0,001		Algorithm converged.	-0,011	0,009	0,91		Algorithm converged.	0,37	2,23	0,8384		1,10		Algorithm converged.	0,45	2,69
		Asia Pacific	482	27,0	7	1,5	517	28,4	7	1,4	1,07		Algorithm converged.	0,37	3,08	0,001		Algorithm converged.	-0,014	0,016	1,07		Algorithm converged.	0,38	3,04	0,8949		0,93		Algorithm converged.	0,33	2,64
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024	2,01		Algorithm converged.	0,18	21,98	0,5670		0,50		Algorithm converged.	0,05	5,44
	PANCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOCYTOPENIA	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	9	3,4	252	13,8	3	1,2	2,95		Algorithm converged.	0,79	11,03	0,022		Algorithm converged.	-0,003	0,048	2,89		Algorithm converged.	0,79	10,54	0,1088	-	0,35		Algorithm converged.	0,09	1,27
		Western Europe	814	45,7	20	2,5	824	45,2	16	1,9	1,27		Algorithm converged.	0,65	2,47	0,005		Algorithm converged.	-0,009	0,019	1,27		Algorithm converged.	0,66	2,42	0,4781		0,79		Algorithm converged.	0,41	1,51
		Asia Pacific	482	27,0	3	0,6	517	28,4	6	1,2	0,53		Algorithm converged.	0,13	2,14	-0,005		Algorithm converged.	-0,017	0,006	0,54		Algorithm converged.	0,13	2,13	0,3763		1,86		Algorithm converged.	0,47	7,41
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	4	2,2	184	10,1	4	2,2	1,01		Algorithm converged.	0,25	4,08	0,000		Algorithm converged.	-0,030	0,030	1,01		Algorithm converged.	0,26	3,96	0,9938		0,99		Algorithm converged.	0,25	3,92
	ACUTE CORONARY SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATRIAL FIBRILLATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATRIAL THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRADYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	USA/Canada	262	14,7	6	2,3	252	13,8	2	0,8	2,93		Algorithm converged.	0,59	14,65	0,015		Algorithm converged.	-0,006	0,036	2,89		Algorithm converged.	0,59	14,16	0,1917	-	0,35		Algorithm converged.	0,07	1,70
		Western Europe	814	45,7	15	1,8	824	45,2	9	1,1	1,70		Algorithm converged.	0,74	3,91	0,008		Algorithm converged.	-0,004	0,019	1,69		Algorithm converged.	0,74	3,83	0,2116		0,59		Algorithm converged.	0,26	1,35
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CARDIAC FAILURE CONGESTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CORONARY ARTERY STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EXTRASYSTOLES	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METABOLIC CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PALPITATIONS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PERICARDIAL EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	SINUS NODE DYSFUNCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	STRESS CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TACHYCARDIA PAROXYSMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENTRICULAR ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR FIBRILLATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
EAR AND LABYRINTH DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	EXTERNAL EAR INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TYMPANIC MEMBRANE PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VERTIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VESTIBULAR DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
ENDOCRINE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GOITRE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	HYPERTHYROIDISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	14	5,3	252	13,8	9	3,6	1,52		Algorithm converged.	0,65	3,59	0,018		Algorithm converged.	-0,018	0,053	1,50		Algorithm converged.	0,66	3,39	0,3351	-	0,67		Algorithm converged.	0,29	1,52	
		Western Europe	814	45,7	45	5,5	824	45,2	32	3,9	1,45		Algorithm converged.	0,91	2,30	0,016		Algorithm converged.	-0,004	0,037	1,42		Algorithm converged.	0,91	2,22	0,1180		0,70		Algorithm converged.	0,45	1,09	
		Asia Pacific	482	27,0	20	4,1	517	28,4	13	2,5	1,68		Algorithm converged.	0,83	3,41	0,016		Algorithm converged.	-0,006	0,039	1,65		Algorithm converged.	0,83	3,28	0,1531		0,61		Algorithm converged.	0,30	1,20	
		Latin America	42	2,4	2	4,8	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	5	2,7	184	10,1	2	1,1	2,56		Algorithm converged.	0,49	13,35	0,016		Algorithm converged.	-0,012	0,044	2,51		Algorithm converged.	0,49	12,79	0,2668		0,40		Algorithm converged.	0,08	2,02	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007	3,04		Algorithm converged.	0,32	29,13	0,3356		0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABDOMINAL PAIN UPPER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 61.844039817 is greater than the limit of 0.0001. The convergence is questionable.	-0,073	0,069	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CONSTIPATION	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	DIARRHOEA	USA/Canada	262	14,7	9	3,4	252	13,8	1	0,4	8,93		Algorithm converged.	1,12	71,00	0,030		Algorithm converged.	0,007	0,054		8,66		Algorithm converged.	1,10	67,83	0,0399	-	0,12		Algorithm converged.	0,01	0,91	
		Western Europe	814	45,7	22	2,7	824	45,2	10	1,2	2,26		Algorithm converged.	1,06	4,81	0,015		Algorithm converged.	0,001	0,028		2,23		Algorithm converged.	1,06	4,67	0,0342		0,45		Algorithm converged.	0,21	0,94	
		Asia Pacific	482	27,0	8	1,7	517	28,4	2	0,4	4,35		Algorithm converged.	0,92	20,57	0,013		Algorithm converged.	0,000	0,025		4,29		Algorithm converged.	0,92	20,10	0,0646		0,23		Algorithm converged.	0,05	1,09	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	2	1,1	184	10,1	1	0,5	2,02		Algorithm converged.	0,18	22,50	0,005		Algorithm converged.	-0,013	0,024		2,01		Algorithm converged.	0,18	21,98	0,5670			0,50		Algorithm converged.	0,05	5,44	
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	DUODENAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DUODENAL ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	ENTERITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	ENTEROCOLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GASTROOESOPHAGEAL REFLUX DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INGUINAL HERNIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NAUSEA	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	4	0,5	824	45,2	4	0,5	1,01		Algorithm converged.	0,25	4,06	0,000		Algorithm converged.	-0,007	0,007	1,01		Algorithm converged.	0,25	4,03	0,9862		0,99		Algorithm converged.	0,25	3,94
		Asia Pacific	482	27,0	5	1,0	517	28,4	4	0,8	1,34		Algorithm converged.	0,36	5,04	0,003		Algorithm converged.	-0,009	0,014	1,34		Algorithm converged.	0,36	4,96	0,6606		0,75		Algorithm converged.	0,20	2,76
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA MOUTH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ORAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PANCREATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	PROCTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	5	0,6	824	45,2	1	0,1	5,09		Algorithm converged.	0,59	43,63	0,005		Algorithm converged.	-0,001	0,011	5,06		Algorithm converged.	0,59	43,23	0,1384		0,20		Algorithm converged.	0,02	1,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBILEUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VOMITING	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	5	0,6	824	45,2	7	0,8	0,72		Algorithm converged.	0,23	2,28	-0,002		Algorithm converged.	-0,011	0,006	0,72		Algorithm converged.	0,23	2,27	0,5784		1,38		Algorithm converged.	0,44	4,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	5	1,0	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	8	3,2	0,59		Algorithm converged.	0,19	1,84	-0,013		Algorithm converged.	-0,040	0,015	0,60		Algorithm converged.	0,20	1,81	0,3662	-	1,66		Algorithm converged.	0,55	5,02
		Western Europe	814	45,7	28	3,4	824	45,2	38	4,6	0,74		Algorithm converged.	0,45	1,21	-0,012		Algorithm converged.	-0,031	0,007	0,75		Algorithm converged.	0,46	1,20	0,2298		1,34		Algorithm converged.	0,83	2,16
		Asia Pacific	482	27,0	10	2,1	517	28,4	5	1,0	2,17		Algorithm converged.	0,74	6,39	0,011		Algorithm converged.	-0,004	0,026	2,15		Algorithm converged.	0,74	6,23	0,1606		0,47		Algorithm converged.	0,16	1,35
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASTHENIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEST PAIN	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,004		Algorithm converged.	-0,010	0,003	0,40		Algorithm converged.	0,08	2,08	0,2790		2,47		Algorithm converged.	0,48	12,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHILLS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	FATIGUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008		1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFLUENZA LIKE ILLNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MASS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	MUCOSAL INFLAMMATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NON-CARDIAC CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYREXIA	USA/Canada	262	14,7	2	0,8	252	13,8	5	2,0	0,38		Algorithm converged.	0,07	1,98	-0,012		Algorithm converged.	-0,032	0,008	0,38		Algorithm converged.	0,08	1,96	0,2509	-	2,60		Algorithm converged.	0,51	13,28

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	17	2,1	824	45,2	26	3,2	0,65		Algorithm converged.	0,35	1,22	-0,011		Algorithm converged.	-0,026	0,005	0,66		Algorithm converged.	0,36	1,21	0,1802		1,51		Algorithm converged.	0,83	2,76
		Asia Pacific	482	27,0	6	1,2	517	28,4	5	1,0	1,29		Algorithm converged.	0,39	4,26	0,003		Algorithm converged.	-0,010	0,016	1,29		Algorithm converged.	0,40	4,19	0,6751		0,78		Algorithm converged.	0,24	2,53
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BILIARY COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHOLANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CHOLECYSTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLELITHIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG-INDUCED LIVER INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FUNCTION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANAPHYLACTIC REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	13	5,0	252	13,8	24	9,5	0,50		Algorithm converged.	0,25	1,00	-0,046		Algorithm converged.	-0,090	-0,001	0,52		Algorithm converged.	0,27	1,00	0,0501	-	1,92		Algorithm converged.	1,00	3,69
		Western Europe	814	45,7	77	9,5	824	45,2	52	6,3	1,55		Algorithm converged.	1,08	2,24	0,031		Algorithm converged.	0,005	0,058	1,50		Algorithm converged.	1,07	2,10	0,0190		0,67		Algorithm converged.	0,48	0,94
		Asia Pacific	482	27,0	29	6,0	517	28,4	31	6,0	1,00		Algorithm converged.	0,60	1,69	0,000		Algorithm converged.	-0,029	0,030	1,00		Algorithm converged.	0,61	1,64	0,9891		1,00		Algorithm converged.	0,61	1,63

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2	2,20		Algorithm converged.	0,19	25,20	0,025		Algorithm converged.	-0,052	0,103		2,14		Algorithm converged.	0,20	22,77	0,5273		0,47		Algorithm converged.	0,04	4,96
		Other	183	10,3	5	2,7	184	10,1	4	2,2	1,26		Algorithm converged.	0,33	4,78	0,006		Algorithm converged.	-0,026	0,037		1,26		Algorithm converged.	0,34	4,61	0,7301		0,80		Algorithm converged.	0,22	2,92
	ABDOMINAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ABSCESS ORAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE HEPATITIS B	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945778 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	ANAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	APPENDICITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BACTERIAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	BREAST CELLULITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CELLULITIS	USA/Canada	262	14,7	3	1,1	252	13,8	6	2,4	0,47		Algorithm converged.	0,12	1,92	-0,012		Algorithm converged.	-0,035	0,010		0,48		Algorithm converged.	0,12	1,90	0,2967	-	2,08		Algorithm converged.	0,53	8,22
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2	2,54		Algorithm converged.	0,49	13,13	0,004		Algorithm converged.	-0,003	0,010		2,53		Algorithm converged.	0,49	13,01	0,2663		0,40		Algorithm converged.	0,08	2,03
		Asia Pacific	482	27,0	5	1,0	517	28,4	4	0,8	1,34		Algorithm converged.	0,36	5,04	0,003		Algorithm converged.	-0,009	0,014		1,34		Algorithm converged.	0,36	4,96	0,6606		0,75		Algorithm converged.	0,20	2,76
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHRONIC SINUSITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk										
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	CLOSTRIDIUM DIFFICILE COLITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	CLOSTRIDIUM DIFFICILE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	4	0,5	824	45,2	2	0,2	2,03		Algorithm converged.	0,37	11,11	0,002		Algorithm converged.	-0,003	0,008	2,02		Algorithm converged.	0,37	11,02	0,4146		0,49		Algorithm converged.	0,09	2,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA INFECTIOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DISSEMINATED TUBERCULOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	3	1,2	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007	1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DIVERTICULITIS INTESTINAL PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ERYSIPELAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2	1,52		Algorithm converged.	0,25	9,12	0,001		Algorithm converged.	-0,004	0,007		1,52		Algorithm converged.	0,25	9,06	0,6468		0,66		Algorithm converged.	0,11	3,93
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ESCHERICHIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	1	0,1	7,14		Algorithm converged.	0,88	58,15	0,007		Algorithm converged.	0,001	0,014	7,09		Algorithm converged.	0,87	57,46	0,0667		0,14		Algorithm converged.	0,02	1,14
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS VIRAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	H1N1 INFLUENZA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HERPES ZOSTER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTED SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	6	0,7	0,50		Algorithm converged.	0,13	2,02	-0,004		Algorithm converged.	-0,011	0,004		0,51		Algorithm converged.	0,13	2,02	0,3344		1,98		Algorithm converged.	0,50	7,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LOCALISED INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	LOWER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	4	0,5	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MASTITIS	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASOPHARYNGITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPENIC SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	3	0,4	2,37		Algorithm converged.	0,61	9,21	0,005		Algorithm converged.	-0,003	0,013	2,36		Algorithm converged.	0,61	9,10	0,2118		0,42		Algorithm converged.	0,11	1,63
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	OTITIS MEDIA ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARONYCHIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERITONSILLAR ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PHLEBITIS INFECTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCYSTIS JIROVECII PNEUMONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	USA/Canada	262	14,7	2	0,8	252	13,8	6	2,4	0,32		Algorithm converged.	0,06	1,58	-0,016		Algorithm converged.	-0,038	0,005	0,32		Algorithm converged.	0,07	1,57	0,1611	-	3,12		Algorithm converged.	0,64	15,31
		Western Europe	814	45,7	6	0,7	824	45,2	8	1,0	0,76		Algorithm converged.	0,26	2,19	-0,002		Algorithm converged.	-0,011	0,007	0,76		Algorithm converged.	0,26	2,18	0,6085		1,32		Algorithm converged.	0,46	3,78

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	7	1,5	517	28,4	6	1,2	1,26		Algorithm converged.	0,42	3,76	0,003		Algorithm converged.	-0,011	0,017	1,25		Algorithm converged.	0,42	3,70	0,6850		0,80		Algorithm converged.	0,27	2,36
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
	PNEUMONIA ASPIRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PSEUDOMONAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS ACUTE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SALPINGO-OOPHORITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEPSIS	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002		0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43	
		Asia Pacific	482	27,0	0	0,0	517	28,4	3	0,6	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SEPTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SERRATIA INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SKIN INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	4	0,5	0,50		Algorithm converged.	0,09	2,76	-0,002		Algorithm converged.	-0,008	0,003		0,51		Algorithm converged.	0,09	2,76	0,4310		1,98		Algorithm converged.	0,36	10,76	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	SOFT TISSUE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE			Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	STREPTOCOCCAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCUTANEOUS ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TONSILLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931			0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TOOTH INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1	3,04		Algorithm converged.	0,32	29,33	0,002		Algorithm converged.	-0,002	0,007		3,04		Algorithm converged.	0,32	29,13	0,3356			0,33		Algorithm converged.	0,03	3,16
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007		0,72		Algorithm converged.	0,12	4,26	0,7127			1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	URINARY TRACT INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009		0,48		Algorithm converged.	0,04	5,27	0,5490			2,08		Algorithm converged.	0,19	22,79

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	2	0,4	517	28,4	3	0,6	0,71		Algorithm converged.	0,12	4,29	-0,002		Algorithm converged.	-0,010	0,007	0,72		Algorithm converged.	0,12	4,26	0,7127		1,40		Algorithm converged.	0,23	8,33
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UROSEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VARICELLA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VASCULAR DEVICE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4	0,34		Algorithm converged.	0,03	3,24	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,24	0,3463		2,96		Algorithm converged.	0,31	28,43
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VULVAL ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	WOUND INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005	1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2	1,29		Algorithm converged.	0,29	5,81	0,003		Algorithm converged.	-0,017	0,023	1,28		Algorithm converged.	0,29	5,67	0,7430	-	0,78		Algorithm converged.	0,18	3,45
		Western Europe	814	45,7	14	1,7	824	45,2	5	0,6	2,87		Algorithm converged.	1,03	8,00	0,011		Algorithm converged.	0,001	0,022	2,83		Algorithm converged.	1,03	7,83	0,0446		0,35		Algorithm converged.	0,13	0,98
		Asia Pacific	482	27,0	5	1,0	517	28,4	7	1,4	0,76		Algorithm converged.	0,24	2,42	-0,003		Algorithm converged.	-0,017	0,010	0,77		Algorithm converged.	0,24	2,40	0,6472		1,31		Algorithm converged.	0,42	4,08
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	3	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACCIDENTAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	AVULSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST PROCEDURAL COMPLICATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	CONCUSSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FALL	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEMORAL NECK FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	FRACTURED SACRUM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GRAFT THROMBOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HUMERUS FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ILIUM FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INFUSION RELATED REACTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTENTIONAL OVERDOSE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	JOINT DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	LOWER LIMB FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE						
	PNEUMOCONIOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOTHORAX TRAUMATIC	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	POST PROCEDURAL HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PROCEDURAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY RADIATION INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RADIUS FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROAD TRAFFIC ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LACERATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SPINAL COMPRESSION FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THERMAL BURN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TIBIA FRACTURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TOXICITY TO VARIOUS AGENTS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND DEHISCENCE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	5	0,6	824	45,2	5	0,6	1,01		Algorithm converged.	0,29	3,51	0,000		Algorithm converged.	-0,007	0,008	1,01		Algorithm converged.	0,29	3,48	0,9845		0,99		Algorithm converged.	0,29	3,40
		Asia Pacific	482	27,0	10	2,1	517	28,4	5	1,0	2,17		Algorithm converged.	0,74	6,39	0,011		Algorithm converged.	-0,004	0,026	2,15		Algorithm converged.	0,74	6,23	0,1606		0,47		Algorithm converged.	0,16	1,35
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EJECTION FRACTION DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	4	0,5	824	45,2	3	0,4	1,35		Algorithm converged.	0,30	6,06	0,001		Algorithm converged.	-0,005	0,008	1,35		Algorithm converged.	0,30	6,01	0,6940		0,74		Algorithm converged.	0,17	3,30

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOGLOBIN DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LIVER FUNCTION TEST INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	5	1,0	517	28,4	2	0,4	2,70		Algorithm converged.	0,52	13,98	0,007		Algorithm converged.	-0,004	0,017	2,68		Algorithm converged.	0,52	13,76	0,2371		0,37		Algorithm converged.	0,07	1,91

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TROPONIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	13	5,0	252	13,8	4	1,6	3,24		Algorithm converged.	1,04	10,06	0,034		Algorithm converged.	0,003	0,064		3,13		Algorithm converged.	1,03	9,46	0,0436	-	0,32		Algorithm converged.	0,11	0,97
		Western Europe	814	45,7	9	1,1	824	45,2	3	0,4	3,06		Algorithm converged.	0,83	11,34	0,007		Algorithm converged.	-0,001	0,016		3,04		Algorithm converged.	0,83	11,18	0,0948		0,33		Algorithm converged.	0,09	1,21
		Asia Pacific	482	27,0	7	1,5	517	28,4	6	1,2	1,26		Algorithm converged.	0,42	3,76	0,003		Algorithm converged.	-0,011	0,017		1,25		Algorithm converged.	0,42	3,70	0,6850		0,80		Algorithm converged.	0,27	2,36
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DECREASED APPETITE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	3	0,6	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
	DEHYDRATION	USA/Canada	262	14,7	7	2,7	252	13,8	2	0,8	3,43		Algorithm converged.	0,71	16,68	0,019		Algorithm converged.	-0,004	0,041	3,37		Algorithm converged.	0,71	16,05	0,1277	-	0,30		Algorithm converged.	0,06	1,42
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE
	DIABETES MELLITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE		NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE		NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ELECTROLYTE IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERKALAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	HYPOCALCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	HYPOGLYCAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOKALAEMIA	USA/Canada	262	14,7	4	1,5	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HYPONATRAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TUMOUR LYSIS SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ARTHRALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BACK PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERVERTEBRAL DISC PROTRUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MUSCULOSKELETAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAIN IN EXTREMITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROTATOR CUFF SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SJOGREN'S SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	3	1,2	0,32		Algorithm converged.	0,03	3,08	-0,008		Algorithm converged.	-0,023	0,007	0,32		Algorithm converged.	0,03	3,06	0,3231	-	3,12		Algorithm converged.	0,33	29,79
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1	0,56		Algorithm converged.	0,19	1,68	-0,005		Algorithm converged.	-0,014	0,004	0,56		Algorithm converged.	0,19	1,67	0,3002		1,78		Algorithm converged.	0,60	5,28
		Asia Pacific	482	27,0	1	0,2	517	28,4	3	0,6	0,36		Algorithm converged.	0,04	3,44	-0,004		Algorithm converged.	-0,011	0,004	0,36		Algorithm converged.	0,04	3,43	0,3724		2,80		Algorithm converged.	0,29	26,80
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYELOID LEUKAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ADENOCARCINOMA PANCREAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BASAL CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BENIGN BREAST NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LENTIGO MALIGNA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG NEOPLASM MALIGNANT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk							
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA IN SITU	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MONOCLONAL GAMMOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MYELODYSPLASTIC SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEURILEMMOMA BENIGN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PAPILLARY THYROID CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PARATHYROID TUMOUR BENIGN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TRANSITIONAL CELL CARCINOMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	UTERINE LEIOMYOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028	1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
		Western Europe	814	45,7	15	1,8	824	45,2	6	0,7	2,56		Algorithm converged.	0,99	6,63	0,011		Algorithm converged.	0,000	0,022	2,53		Algorithm converged.	0,99	6,49	0,0533		0,40		Algorithm converged.	0,15	1,01
		Asia Pacific	482	27,0	4	0,8	517	28,4	7	1,4	0,61		Algorithm converged.	0,18	2,10	-0,005		Algorithm converged.	-0,018	0,008	0,61		Algorithm converged.	0,18	2,08	0,4324		1,63		Algorithm converged.	0,48	5,54
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ATAXIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBRAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIZZINESS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2	1,07		Algorithm converged.	0,07	17,20	0,000		Algorithm converged.	-0,005	0,006	1,07		Algorithm converged.	0,07	17,10	0,9604		0,93		Algorithm converged.	0,06	14,86
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEAD TITUBATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO								PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HEADACHE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERCOSTAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LOSS OF CONSCIOUSNESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	NEUROPATHY PERIPHERAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	NEUROTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARAESTHESIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PSYCHOGENIC SEIZURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	SEIZURE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SYNCOPE	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	6	0,7	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4	0,54		Algorithm converged.	0,05	5,92	-0,002		Algorithm converged.	-0,009	0,005	0,54		Algorithm converged.	0,05	5,90	0,6105		1,86		Algorithm converged.	0,17	20,50
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THALAMIC INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRANSIENT ISCHAEMIC ATTACK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TRIGEMINAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
PRODUCT ISSUE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE DISLOCATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE EXTRUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5	0,76		Algorithm converged.	0,17	3,40	-0,001		Algorithm converged.	-0,007	0,005	0,76		Algorithm converged.	0,17	3,38	0,7178		1,32		Algorithm converged.	0,30	5,87
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ANXIETY	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009		2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MAJOR DEPRESSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	MENTAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PERSISTENT DEPRESSIVE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSONALITY CHANGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003		1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDE ATTEMPT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2	0,96		Algorithm converged.	0,19	4,81	0,000		Algorithm converged.	-0,019	0,018	0,96		Algorithm converged.	0,20	4,72	0,9618	-	1,04		Algorithm converged.	0,21	5,10
		Western Europe	814	45,7	3	0,4	824	45,2	3	0,4	1,01		Algorithm converged.	0,20	5,03	0,000		Algorithm converged.	-0,006	0,006	1,01		Algorithm converged.	0,20	5,00	0,9880		0,99		Algorithm converged.	0,20	4,88
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8	1,45		Algorithm converged.	0,24	8,74	0,004		Algorithm converged.	-0,013	0,020	1,44		Algorithm converged.	0,24	8,56	0,6866	-	0,69		Algorithm converged.	0,12	4,11
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DYSURIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RENAL COLIC	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RENAL FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	RENAL IMPAIRMENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	URETERIC OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	URINARY INCONTINENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	URINARY RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021	1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	BREAST INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CERVICAL POLYP	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEAVY MENSTRUAL BLEEDING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OVARIAN CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PELVIC CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VAGINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	4	1,6	1,21		Algorithm converged.	0,32	4,54	0,003		Algorithm converged.	-0,019	0,026	1,20		Algorithm converged.	0,33	4,43	0,7818	-	0,83		Algorithm converged.	0,23	3,06
		Western Europe	814	45,7	12	1,5	824	45,2	14	1,7	0,87		Algorithm converged.	0,40	1,88	-0,002		Algorithm converged.	-0,014	0,010	0,87		Algorithm converged.	0,40	1,86	0,7161		1,15		Algorithm converged.	0,54	2,48
		Asia Pacific	482	27,0	0	0,0	517	28,4	4	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
		Other	183	10,3	2	1,1	184	10,1	3	1,6	0,67		Algorithm converged.	0,11	4,04	-0,005		Algorithm converged.	-0,029	0,018	0,67		Algorithm converged.	0,11	3,96	0,6591		1,49		Algorithm converged.	0,25	8,82
	ASTHMA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHIECTASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BRONCHOSPASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	COUGH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	DYSPHONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	DYSPNOEA	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8	0,48		Algorithm converged.	0,04	5,31	-0,004		Algorithm converged.	-0,017	0,009	0,48		Algorithm converged.	0,04	5,27	0,5490	-	2,08		Algorithm converged.	0,19	22,79
		Western Europe	814	45,7	2	0,2	824	45,2	5	0,6	0,40		Algorithm converged.	0,08	2,09	-0,004		Algorithm converged.	-0,010	0,003	0,40		Algorithm converged.	0,08	2,08	0,2790		2,47		Algorithm converged.	0,48	12,69
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE
	DYSPNOEA EXERTIONAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-				NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE					NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	EPISTAXIS	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTERSTITIAL LUNG DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG INFILTRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NASAL OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NASAL POLYPS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL EFFUSION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2	0,51		Algorithm converged.	0,05	5,59	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,57	0,5779		1,98		Algorithm converged.	0,18	21,75
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PNEUMOTHORAX	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY EMBOLISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2	1,01		Algorithm converged.	0,14	7,20	0,000		Algorithm converged.	-0,005	0,005		1,01		Algorithm converged.	0,14	7,17	0,9902		0,99		Algorithm converged.	0,14	7,00
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	1	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	7	0,9	824	45,2	2	0,2	3,57		Algorithm converged.	0,74	17,21	0,006		Algorithm converged.	-0,001	0,013	3,54		Algorithm converged.	0,74	17,00	0,1139		0,28		Algorithm converged.	0,06	1,35
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008	1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 112.56362484 is greater than the limit of 0.0001. The convergence is questionable.	-0,072	0,070	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS ACNEIFORM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RASH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	RASH MACULAR	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SKIN ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	TOXIC SKIN ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	URTICARIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
SURGICAL AND MEDICAL PROCEDURE	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BREAST TUMOUR EXCISION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HOSPITALISATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	7	2,8	0,68		Algorithm converged.	0,21	2,17	-0,009		Algorithm converged.	-0,035	0,018	0,69		Algorithm converged.	0,22	2,14	0,5167	-	1,46		Algorithm converged.	0,47	4,53

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	7	0,9	824	45,2	8	1,0	0,88		Algorithm converged.	0,32	2,45	-0,001		Algorithm converged.	-0,010	0,008		0,89		Algorithm converged.	0,32	2,43	0,8138		1,13		Algorithm converged.	0,41	3,10
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4	1,07		Algorithm converged.	0,15	7,65	0,000		Algorithm converged.	-0,008	0,008		1,07		Algorithm converged.	0,15	7,58	0,9440		0,93		Algorithm converged.	0,13	6,59
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	2	1,1	184	10,1	2	1,1	1,01		Algorithm converged.	0,14	7,22	0,000		Algorithm converged.	-0,021	0,021		1,01		Algorithm converged.	0,14	7,06	0,9956		0,99		Algorithm converged.	0,14	6,99
	AXILLARY VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DEEP VEIN THROMBOSIS	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4	1,93		Algorithm converged.	0,17	21,43	0,004		Algorithm converged.	-0,009	0,017		1,92		Algorithm converged.	0,18	21,08	0,5923	-	0,52		Algorithm converged.	0,05	5,70
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4	0,96		Algorithm converged.	0,06	15,46	0,000		Algorithm converged.	-0,011	0,011	0,96		Algorithm converged.	0,06	15,29	0,9780	-	1,04		Algorithm converged.	0,07	16,53
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1	2,03		Algorithm converged.	0,18	22,40	0,001		Algorithm converged.	-0,003	0,005	2,02		Algorithm converged.	0,18	22,28	0,5644		0,49		Algorithm converged.	0,04	5,44
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	EMBOLISM VENOUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	2	1,1	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOTENSION	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8	0,96		Algorithm converged.	0,13	6,88	0,000		Algorithm converged.	-0,016	0,015	0,96		Algorithm converged.	0,14	6,78	0,9688	-	1,04		Algorithm converged.	0,15	7,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 105.52839829 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,068		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LYMPHOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 120.60388376 is greater than the limit of 0.0001. The convergence is questionable.	-0,075	0,072	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1	1,01		Algorithm converged.	0,06	16,21	0,000		Algorithm converged.	-0,003	0,003	1,01		Algorithm converged.	0,06	16,16	0,9931		0,99		Algorithm converged.	0,06	15,77
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOSIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 57.978787329 is greater than the limit of 0.0001. The convergence is questionable.	-0,071	0,066	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VARICOSE VEIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	0	0,0	184	10,1	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	VENOUS THROMBOSIS LIMB	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AESAE_S1.xls
05MAY2022 18:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	5	11,9	0,99		Algorithm converged.	0,28	3,49	-0,001		Algorithm converged.	-0,133	0,131	0,99		Algorithm converged.	0,32	3,01	0,9834	0,0715	1,01		Algorithm converged.	0,33	3,08
		0 positive nodes, tumor > 1 cm	259	14,5	30	11,6	271	14,9	22	8,1	1,48		Algorithm converged.	0,83	2,64	0,035		Algorithm converged.	-0,016	0,085	1,43		Algorithm converged.	0,85	2,41	0,1829		0,70		Algorithm converged.	0,42	1,18
		1-3 positive nodes	891	50,0	107	12,0	905	49,7	89	9,8	1,25		Algorithm converged.	0,93	1,69	0,022		Algorithm converged.	-0,007	0,051	1,22		Algorithm converged.	0,94	1,59	0,1403		0,82		Algorithm converged.	0,63	1,07
		>= 4 positive nodes	582	32,6	49	8,4	604	33,2	70	11,6	0,70		Algorithm converged.	0,48	1,03	-0,032		Algorithm converged.	-0,066	0,002	0,73		Algorithm converged.	0,51	1,03	0,0710		1,38		Algorithm converged.	0,97	1,95
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	5	0,8	0,62		Algorithm converged.	0,15	2,61	-0,003		Algorithm converged.	-0,012	0,006	0,62		Algorithm converged.	0,15	2,59	0,5152		1,61		Algorithm converged.	0,39	6,69

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009	2,54		Algorithm converged.	0,49	13,05	0,2646		0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	6	11,8	42	2,3	4	9,5	1,27		Algorithm converged.	0,33	4,82	0,022		Algorithm converged.	-0,103	0,148	1,24		Algorithm converged.	0,37	4,09	0,7294	0,3431	0,81		Algorithm converged.	0,24	2,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	21	8,1	271	14,9	14	5,2	1,62		Algorithm converged.	0,81	3,26	0,029		Algorithm converged.	-0,013	0,072		1,57		Algorithm converged.	0,82	3,02	0,1770			0,64		Algorithm converged.	0,33	1,23	
		1-3 positive nodes	891	50,0	88	9,9	905	49,7	76	8,4	1,20		Algorithm converged.	0,87	1,65	0,015		Algorithm converged.	-0,012	0,041		1,18		Algorithm converged.	0,88	1,58	0,2774			0,85		Algorithm converged.	0,63	1,14	
		>= 4 positive nodes	582	32,6	39	6,7	604	33,2	49	8,1	0,81		Algorithm converged.	0,53	1,26	-0,014		Algorithm converged.	-0,044	0,016		0,83		Algorithm converged.	0,55	1,24	0,3548			1,21		Algorithm converged.	0,81	1,81	
	HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE	
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1	0,35		Algorithm converged.	0,04	3,35	-0,007		Algorithm converged.	-0,022	0,007		0,35		Algorithm converged.	0,04	3,33	0,3603			2,87		Algorithm converged.	0,30	27,39	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LYMPHADENOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3	0,52		Algorithm converged.	0,05	5,73	-0,002		Algorithm converged.	-0,007	0,004	0,52		Algorithm converged.	0,05	5,71	0,5918		1,93		Algorithm converged.	0,18	21,20
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	8	0,9	1,14		Algorithm converged.	0,44	2,98	0,001		Algorithm converged.	-0,008	0,010	1,14		Algorithm converged.	0,44	2,95	0,7827		0,88		Algorithm converged.	0,34	2,26
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	11	1,8	0,28		Algorithm converged.	0,08	1,01	-0,013		Algorithm converged.	-0,025	-0,001	0,28		Algorithm converged.	0,08	1,01	0,0517		3,53		Algorithm converged.	0,99	12,60

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PANCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	4	1,5	1,05		Algorithm converged.	0,26	4,23	0,001		Algorithm converged.	-0,020	0,021	1,05		Algorithm converged.	0,26	4,14	0,9485		0,96		Algorithm converged.	0,24	3,78
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	17	1,9	0,83		Algorithm converged.	0,41	1,70	-0,003		Algorithm converged.	-0,015	0,009	0,84		Algorithm converged.	0,41	1,69	0,6177		1,20		Algorithm converged.	0,59	2,41
		>= 4 positive nodes	582	32,6	18	3,1	604	33,2	8	1,3	2,38		Algorithm converged.	1,03	5,51	0,018		Algorithm converged.	0,001	0,034	2,34		Algorithm converged.	1,02	5,33	0,0439		0,43		Algorithm converged.	0,19	0,98
	ACUTE CORONARY SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ACUTE MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	ANGINA PECTORIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	ATRIAL FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ATRIAL THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BRADYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017		2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	7	0,8	1,46		Algorithm converged.	0,55	3,84	0,003		Algorithm converged.	-0,005	0,012		1,45		Algorithm converged.	0,55	3,80	0,4479		0,69		Algorithm converged.	0,26	1,80
		>= 4 positive nodes	582	32,6	13	2,2	604	33,2	5	0,8	2,74		Algorithm converged.	0,97	7,73	0,014		Algorithm converged.	0,000	0,028		2,70		Algorithm converged.	0,97	7,52	0,0577		0,37		Algorithm converged.	0,13	1,03
	CARDIAC FAILURE CONGESTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CORONARY ARTERY STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	EXTRASYSTOLES	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	METABOLIC CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALPITATIONS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PERICARDIAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SINUS NODE DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	STRESS CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	TACHYCARDIA PAROXYSMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VENTRICULAR ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VENTRICULAR FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
CONGENITAL, FAMILIAL AND GENETIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYLORIC STENOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE		
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE		
EAR AND LABYRINTH DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133902 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374		NE		Algorithm converged.	NE	NE	NE	-		NE		Algorithm converged.	NE	NE		

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	EXTERNAL EAR INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TYMPANIC MEMBRANE PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VERTIGO	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	VESTIBULAR DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
ENDOCRINE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	GOITRE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTHYROIDISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	THYROID DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133992 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	9	3,5	271	14,9	7	2,6	1,36		Algorithm converged.	0,50	3,70	0,009		Algorithm converged.	-0,020	0,038	1,35		Algorithm converged.	0,51	3,56	0,5502		0,74		Algorithm converged.	0,28	1,97	
		1-3 positive nodes	891	50,0	49	5,5	905	49,7	32	3,5	1,59		Algorithm converged.	1,01	2,50	0,020		Algorithm converged.	0,000	0,039	1,56		Algorithm converged.	1,01	2,40	0,0470		0,64		Algorithm converged.	0,42	0,99	
		>= 4 positive nodes	582	32,6	26	4,5	604	33,2	17	2,8	1,61		Algorithm converged.	0,87	3,01	0,017		Algorithm converged.	-0,005	0,038	1,59		Algorithm converged.	0,87	2,89	0,1317		0,63		Algorithm converged.	0,35	1,15	
	ABDOMINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	ABDOMINAL PAIN UPPER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	4	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	CONSTIPATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005		2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024		1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
		1-3 positive nodes	891	50,0	22	2,5	905	49,7	7	0,8	3,25		Algorithm converged.	1,38	7,64	0,017		Algorithm converged.	0,005	0,029		3,19		Algorithm converged.	1,37	7,44	0,0071		0,31		Algorithm converged.	0,13	0,73
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	4	0,7	3,70		Algorithm converged.	1,21	11,30	0,017		Algorithm converged.	0,003	0,031		3,63		Algorithm converged.	1,20	10,97	0,0222		0,28		Algorithm converged.	0,09	0,83
	DIVERTICULUM INTESTINAL HAEMORRHAGIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	DUODENAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DUODENAL ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	ENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ENTEROCOLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROINTESTINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROINTESTINAL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROOESOPHAGEAL REFLUX DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHOIDAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HAEMORRHOIDS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	INGUINAL HERNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTESTINAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTUSSUSCEPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	LOWER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	NAUSEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	5	0,6	1,63		Algorithm converged.	0,53	5,00	0,003		Algorithm converged.	-0,004	0,011		1,63		Algorithm converged.	0,53	4,95	0,3927		0,62		Algorithm converged.	0,20	1,87	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	5	0,8	0,21		Algorithm converged.	0,02	1,77	-0,007		Algorithm converged.	-0,015	0,001		0,21		Algorithm converged.	0,02	1,77	0,1506		4,82		Algorithm converged.	0,56	41,11	
	OEDEMA MOUTH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ORAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PANCREATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PANCREATITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874800164 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SMALL INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STOMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBILEUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VOMITING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	5	0,6	2,04		Algorithm converged.	0,70	6,00	0,006		Algorithm converged.	-0,003	0,014	2,03		Algorithm converged.	0,70	5,92	0,1940		0,49		Algorithm converged.	0,17	1,43
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	4	0,7	0,78		Algorithm converged.	0,17	3,49	-0,001		Algorithm converged.	-0,010	0,007	0,78		Algorithm converged.	0,17	3,46	0,7421		1,28		Algorithm converged.	0,29	5,72
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,061	*	WARNING: The relative Hessian convergence criterion of 4.9114133947 is greater than the limit of 0.0001. The convergence is questionable.	-0,252	0,374	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	6	2,2	1,05		Algorithm converged.	0,33	3,29	0,001		Algorithm converged.	-0,024	0,026	1,05		Algorithm converged.	0,34	3,20	0,9368		0,96		Algorithm converged.	0,31	2,93

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	20	2,2	905	49,7	29	3,2	0,69		Algorithm converged.	0,39	1,24	-0,010		Algorithm converged.	-0,025	0,005	0,70		Algorithm converged.	0,40	1,23	0,2145		1,43		Algorithm converged.	0,81	2,50
		>= 4 positive nodes	582	32,6	17	2,9	604	33,2	19	3,1	0,93		Algorithm converged.	0,48	1,80	-0,002		Algorithm converged.	-0,022	0,017	0,93		Algorithm converged.	0,49	1,77	0,8216		1,08		Algorithm converged.	0,57	2,05
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3	0,34		Algorithm converged.	0,04	3,25	-0,002		Algorithm converged.	-0,007	0,002	0,34		Algorithm converged.	0,04	3,25	0,3479		2,95		Algorithm converged.	0,31	28,34

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	CHILLS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DEVICE RELATED THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798			1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247			0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
	INFLUENZA LIKE ILLNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MALAISE																										-					
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	MASS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	MUCOSAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	NON-CARDIAC CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	OEDEMA PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	PYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	5	1,8	0,41		Algorithm converged.	0,08	2,15	-0,011		Algorithm converged.	-0,030	0,009	0,42		Algorithm converged.	0,08	2,14	0,2952		2,39		Algorithm converged.	0,47	12,21	
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	20	2,2	0,60		Algorithm converged.	0,29	1,24	-0,009		Algorithm converged.	-0,021	0,004	0,61		Algorithm converged.	0,30	1,24	0,1714		1,64		Algorithm converged.	0,81	3,34	
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	12	2,0	0,95		Algorithm converged.	0,42	2,17	-0,001		Algorithm converged.	-0,017	0,015	0,95		Algorithm converged.	0,42	2,14	0,9039		1,05		Algorithm converged.	0,47	2,36	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82	
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	BILIARY COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CHOLECYSTITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CHOLELITHIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DRUG-INDUCED LIVER INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HEPATIC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATIC FUNCTION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	4	0,4	1,53		Algorithm converged.	0,43	5,43	0,002		Algorithm converged.	-0,005	0,009	1,52		Algorithm converged.	0,43	5,38	0,5131		0,66		Algorithm converged.	0,19	2,32
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	ANAPHYLACTIC REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 66.800849632 is greater than the limit of 0.0001. The convergence is questionable.	-0,070	0,066		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,003	*	WARNING: The relative Hessian convergence criterion of 45.078386058 is greater than the limit of 0.0001. The convergence is questionable.	-0,062	0,069	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007	1,04		Algorithm converged.	0,15	7,34	0,9704		0,96		Algorithm converged.	0,14	6,82
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	6	14,3	0,51		Algorithm converged.	0,13	1,95	-0,064		Algorithm converged.	-0,193	0,065	0,55		Algorithm converged.	0,17	1,82	0,3264	0,6577	1,82		Algorithm converged.	0,55	6,03
		0 positive nodes, tumor > 1 cm	259	14,5	17	6,6	271	14,9	15	5,5	1,20		Algorithm converged.	0,59	2,45	0,010		Algorithm converged.	-0,030	0,051	1,19		Algorithm converged.	0,60	2,32	0,6197		0,84		Algorithm converged.	0,43	1,65
		1-3 positive nodes	891	50,0	61	6,8	905	49,7	51	5,6	1,23		Algorithm converged.	0,84	1,81	0,012		Algorithm converged.	-0,010	0,034	1,21		Algorithm converged.	0,85	1,74	0,2896		0,82		Algorithm converged.	0,57	1,18
		>= 4 positive nodes	582	32,6	44	7,6	604	33,2	40	6,6	1,15		Algorithm converged.	0,74	1,80	0,009		Algorithm converged.	-0,020	0,039	1,14		Algorithm converged.	0,76	1,72	0,5295		0,88		Algorithm converged.	0,58	1,32

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ABDOMINAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ABSCESS ORAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ACUTE HEPATITIS B	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ANAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	APPENDICITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	APPENDICITIS PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE		NE	NE			
	BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE		NE	NE			
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE		NE	NE			
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE		NE	NE			
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37		
	BACTERIAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE		NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801536 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	BREAST ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	BREAST CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791			0,96		Algorithm converged.	0,06	15,37						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	BRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008		2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	7	1,2	1,04		Algorithm converged.	0,36	2,98	0,000		Algorithm converged.	-0,012	0,013	1,04		Algorithm converged.	0,37	2,94	0,9443		0,96		Algorithm converged.	0,34	2,73
	CHRONIC SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	CLOSTRIDIUM DIFFICILE COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CLOSTRIDIUM DIFFICILE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	DEVICE RELATED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE RELATED SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DIARRHOEA INFECTIOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00			Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DISSEMINATED TUBERCULOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DIVERTICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	DIVERTICULITIS INTESTINAL PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ERYSIPELAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-		>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912			0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	ESCHERICHIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTROENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010	5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	GASTROENTERITIS VIRAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	H1N1 INFLUENZA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HEPATITIS B REACTIVATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HERPES ZOSTER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTED LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	INFECTED SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	5	0,8	0,41		Algorithm converged.	0,08	2,14	-0,005		Algorithm converged.	-0,013	0,004	0,42		Algorithm converged.	0,08	2,13	0,2922		2,41		Algorithm converged.	0,47	12,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOCALISED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2	2,04		Algorithm converged.	0,37	11,14	0,002		Algorithm converged.	-0,003	0,008	2,03		Algorithm converged.	0,37	11,06	0,4124		0,49		Algorithm converged.	0,09	2,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LYMPHANGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE			Algorithm converged.	NE	NE	NE		NE			Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE		NE				NE	NE
	MASTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE	-	NE				NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE				NE	NE	NE		NE				NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	NASOPHARYNGITIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUTROPENIC INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	NEUTROPENIC SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1	4,08		Algorithm converged.	0,45	36,54	0,003		Algorithm converged.	-0,002	0,008	4,06		Algorithm converged.	0,45	36,28	0,2095		0,25		Algorithm converged.	0,03	2,20
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010	3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	OTITIS MEDIA ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	PARONYCHIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERIODONTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERITONSILLAR ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	PHLEBITIS INFECTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PLEURAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PNEUMOCYSTIS JIROVECII PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011		0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	11	1,2	0,64		Algorithm converged.	0,25	1,67	-0,004		Algorithm converged.	-0,013	0,005		0,65		Algorithm converged.	0,25	1,66	0,3645		1,55		Algorithm converged.	0,60	3,97
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	5	0,8	1,25		Algorithm converged.	0,38	4,11	0,002		Algorithm converged.	-0,009	0,013		1,25		Algorithm converged.	0,38	4,06	0,7158		0,80		Algorithm converged.	0,25	2,62
	PNEUMONIA ASPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	PNEUMONIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMONIA PNEUMOCOCCAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	POSTOPERATIVE WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PSEUDOMONAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PYELONEPHRITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PYELONEPHRITIS ACUTE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	RECTAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SALPINGO-OOPHORITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004	0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	4	0,7	0,52		Algorithm converged.	0,09	2,83	-0,003		Algorithm converged.	-0,011	0,005	0,52		Algorithm converged.	0,10	2,82	0,4477		1,93		Algorithm converged.	0,35	10,48
	SEPTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SERRATIA INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	SINUSITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,024	*	WARNING: The relative Hessian convergence criterion of 30.874801744 is greater than the limit of 0.0001. The convergence is questionable.	-0,061	0,110	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	5	0,6	0,20		Algorithm converged.	0,02	1,73	-0,004		Algorithm converged.	-0,010	0,001	0,20		Algorithm converged.	0,02	1,74	0,1453		4,92		Algorithm converged.	0,58	42,05

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SOFT TISSUE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STAPHYLOCOCCAL SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	STREPTOCOCCAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUBCUTANEOUS ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TONSILLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOOTH INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962948 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962939 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3	1,02		Algorithm converged.	0,20	5,05	0,000		Algorithm converged.	-0,005	0,005	1,02		Algorithm converged.	0,21	5,02	0,9847		0,98		Algorithm converged.	0,20	4,86
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VARICELLA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	VASCULAR DEVICE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003	0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	VULVAL ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WOUND INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	1	0,4	6,40		Algorithm converged.	0,77	53,56	0,019		Algorithm converged.	0,000	0,039		6,28		Algorithm converged.	0,76	51,79	0,0880		0,16		Algorithm converged.	0,02	1,31
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	9	1,0	1,36		Algorithm converged.	0,57	3,24	0,004		Algorithm converged.	-0,006	0,013		1,35		Algorithm converged.	0,57	3,20	0,4891		0,74		Algorithm converged.	0,31	1,74
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	8	1,3	0,78		Algorithm converged.	0,27	2,25	-0,003		Algorithm converged.	-0,015	0,009		0,78		Algorithm converged.	0,27	2,23	0,6407		1,28		Algorithm converged.	0,45	3,68
	ACCIDENTAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	AVULSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	BREAST PROCEDURAL COMPLICATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CONCUSSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FALL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FEMORAL NECK FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	FRACTURED SACRUM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	GRAFT THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
	HUMERUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE						
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2	2,08		Algorithm converged.	0,19	22,99	0,002		Algorithm converged.	-0,004	0,008	2,08		Algorithm converged.	0,19	22,83	0,5506		0,48		Algorithm converged.	0,04	5,30
	ILIUM FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INFUSION RELATED REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	INTENTIONAL OVERDOSE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	JOINT DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LOWER LIMB FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PNEUMOCONIOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PNEUMOTHORAX TRAUMATIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	POST PROCEDURAL HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	POST PROCEDURAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PROCEDURAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY RADIATION INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	RADIUS FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE			
	ROAD TRAFFIC ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE			

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SEROMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 62.625796 53 is greater than the limit of 0.0001. The convergence is questionable.	-0,068	0,064	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SKIN LACERATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	SPINAL COMPRESSION FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THERMAL BURN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TIBIA FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXICITY TO VARIOUS AGENTS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	WOUND DEHISCENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1	2,03		Algorithm converged.	0,18	22,47	0,001		Algorithm converged.	-0,003	0,005	2,03		Algorithm converged.	0,18	22,36	0,5625		0,49		Algorithm converged.	0,04	5,42
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	WRIST FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7	2,65		Algorithm converged.	0,51	13,77	0,012		Algorithm converged.	-0,008	0,032	2,62		Algorithm converged.	0,51	13,36	0,2479		0,38		Algorithm converged.	0,07	1,95
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	6	0,7	1,70		Algorithm converged.	0,62	4,70	0,005		Algorithm converged.	-0,004	0,013	1,69		Algorithm converged.	0,62	4,64	0,3060		0,59		Algorithm converged.	0,22	1,62
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	BLOOD GLUCOSE FLUCTUATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	EJECTION FRACTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	2	0,2	2,55		Algorithm converged.	0,49	13,17	0,003		Algorithm converged.	-0,002	0,009		2,54		Algorithm converged.	0,49	13,05	0,2646			0,39		Algorithm converged.	0,08	2,02
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	2	0,3	1,04		Algorithm converged.	0,15	7,39	0,000		Algorithm converged.	-0,006	0,007		1,04		Algorithm converged.	0,15	7,34	0,9704			0,96		Algorithm converged.	0,14	6,82

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	HAEMOGLOBIN DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LIVER FUNCTION TEST INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TROPONIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	4	1,5	1,31		Algorithm converged.	0,35	4,95	0,005		Algorithm converged.	-0,018	0,027	1,31		Algorithm converged.	0,36	4,82	0,6865		0,76		Algorithm converged.	0,21	2,82
		1-3 positive nodes	891	50,0	17	1,9	905	49,7	3	0,3	5,85		Algorithm converged.	1,71	20,03	0,016		Algorithm converged.	0,006	0,025	5,76		Algorithm converged.	1,69	19,57	0,0051		0,17		Algorithm converged.	0,05	0,59

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	8	1,4	604	33,2	4	0,7	2,09		Algorithm converged.	0,63	6,98	0,007		Algorithm converged.	-0,004	0,019		2,08		Algorithm converged.	0,63	6,86	0,2310		0,48		Algorithm converged.	0,15	1,59
	DECREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	2	4,8	0,00		Algorithm converged.	0,00	NE	-0,069	*	WARNING: The relative Hessian convergence criterion of 6.2626150705 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,220		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	1	0,1	7,16		Algorithm converged.	0,88	58,30	0,007		Algorithm converged.	0,001	0,013		7,11		Algorithm converged.	0,88	57,67	0,0663		0,14		Algorithm converged.	0,02	1,14	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821801 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIABETES MELLITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ELECTROLYTE IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	FLUID RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.36813159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	HYPOGLYCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	1	0,1	5,10		Algorithm converged.	0,59	43,75	0,005		Algorithm converged.	-0,001	0,010	5,08		Algorithm converged.	0,59	43,38	0,1376		0,20		Algorithm converged.	0,02	1,68
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPONATRAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPOVOLAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TUMOUR LYSIS SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5	0,69		Algorithm converged.	0,12	4,15	-0,002		Algorithm converged.	-0,009	0,006	0,69		Algorithm converged.	0,12	4,13	0,6860		1,45		Algorithm converged.	0,24	8,62
	ARTHRALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	BACK PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	INTERVERTEBRAL DISC PROTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	MUSCULOSKELETAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PAIN IN EXTREMITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ROTATOR CUFF SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SJOGREN'S SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	2	0,7	1,05		Algorithm converged.	0,15	7,49	0,000		Algorithm converged.	-0,014	0,015	1,05		Algorithm converged.	0,15	7,37	0,9637		0,96		Algorithm converged.	0,14	6,73
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	10	1,1	0,30		Algorithm converged.	0,08	1,10	-0,008		Algorithm converged.	-0,015	0,000	0,30		Algorithm converged.	0,08	1,10	0,0703		3,28		Algorithm converged.	0,91	11,88
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
	ACUTE MYELOID LEUKAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	ADENOCARCINOMA PANCREAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BASAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BENIGN BREAST NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	GASTRIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	INTRADUCTAL PROLIFERATIVE BREAST LESION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	LENTIGO MALIGNA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LUNG NEOPLASM MALIGNANT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MALIGNANT MELANOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4	0,00		Algorithm converged.	0,00	NE	-0,046	*	WARNING: The relative Hessian convergence criterion of 10.339962958 is greater than the limit of 0.0001. The convergence is questionable.	-0,334	0,241		0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	MALIGNANT MELANOMA IN SITU	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENINGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	MONOCLONAL GAMMOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	MYELODYSPLASTIC SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NEURILEMMOMA BENIGN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PAPILLARY THYROID CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PARATHYROID TUMOUR BENIGN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PELVIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO									PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SMALL CELL LUNG CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SQUAMOUS CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	TRANSITIONAL CELL CARCINOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368133159 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	UTERINE LEIOMYOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5	0,52		Algorithm converged.	0,09	2,86	-0,007		Algorithm converged.	-0,025	0,011	0,52		Algorithm converged.	0,10	2,83	0,4521		1,91		Algorithm converged.	0,35	10,35
		1-3 positive nodes	891	50,0	14	1,6	905	49,7	7	0,8	2,05		Algorithm converged.	0,82	5,10	0,008		Algorithm converged.	-0,002	0,018	2,03		Algorithm converged.	0,82	5,01	0,1238		0,49		Algorithm converged.	0,20	1,21
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	5	0,8	1,88		Algorithm converged.	0,63	5,65	0,007		Algorithm converged.	-0,005	0,020	1,87		Algorithm converged.	0,63	5,54	0,2600		0,54		Algorithm converged.	0,18	1,59
	ATAXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	CEREBRAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DIZZINESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011	1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HAEMORRHAGE INTRACRANIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HEAD TITUBATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999			Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	INTERCOSTAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LOSS OF CONSCIOUSNESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
	NEUROPATHY PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	NEUROTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	PARAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOGENIC SEIZURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SEIZURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,027	*	WARNING: The relative Hessian convergence criterion of 24.527821801 is greater than the limit of 0.0001. The convergence is questionable.	-0,058	0,112	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	THALAMIC INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRANSIENT ISCHAEMIC ATTACK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	TRIGEMINAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
PRODUCT ISSUE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE DISLOCATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	DEVICE EXTRUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	4	0,4	1,78		Algorithm converged.	0,52	6,11	0,003		Algorithm converged.	-0,004	0,011	1,78		Algorithm converged.	0,52	6,05	0,3574		0,56		Algorithm converged.	0,17	1,92
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5	0,34		Algorithm converged.	0,04	3,32	-0,003		Algorithm converged.	-0,010	0,003	0,35		Algorithm converged.	0,04	3,32	0,3573		2,89		Algorithm converged.	0,30	27,71
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1	3,05		Algorithm converged.	0,32	29,42	0,002		Algorithm converged.	-0,002	0,007	3,05		Algorithm converged.	0,32	29,24	0,3342		0,33		Algorithm converged.	0,03	3,15
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	MAJOR DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PERSISTENT DEPRESSIVE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PERSONALITY CHANGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	PSYCHOTIC DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	REACTIVE PSYCHOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	SUICIDAL IDEATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	SUICIDE ATTEMPT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)			Convergence Reason	95% Lower CL	95% Upper CL			Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE					
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE					
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE					

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	2	0,2	1,02		Algorithm converged.	0,14	7,23	0,000		Algorithm converged.	-0,004	0,004	1,02		Algorithm converged.	0,14	7,19	0,9875		0,98		Algorithm converged.	0,14	6,97
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	5	0,8	0,83		Algorithm converged.	0,22	3,10	-0,001		Algorithm converged.	-0,011	0,008	0,83		Algorithm converged.	0,22	3,08	0,7807		1,20		Algorithm converged.	0,33	4,46
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2	3,12		Algorithm converged.	0,32	30,12	0,003		Algorithm converged.	-0,003	0,010		3,11		Algorithm converged.	0,32	29,85	0,3247		0,32		Algorithm converged.	0,03	3,08
	DYSURIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL COLIC	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	RENAL FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131875 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RENAL IMPAIRMENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URETERIC OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	URINARY INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	URINARY RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative e Risk	Relative Risk									
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	2	0,3	1,56		Algorithm converged.	0,26	9,37	0,002		Algorithm converged.	-0,006	0,009	1,56		Algorithm converged.	0,26	9,28	0,6271		0,64		Algorithm converged.	0,11	3,83						
	BREAST INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
	BREAST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CERVICAL POLYP	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	HEAVY MENSTRUAL BLEEDING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	OVARIAN CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	PELVIC CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE						
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	VAGINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086		1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	5	1,8	1,05		Algorithm converged.	0,30	3,66	0,001		Algorithm converged.	-0,022	0,024		1,05		Algorithm converged.	0,31	3,57	0,9424		0,96		Algorithm converged.	0,28	3,26
		1-3 positive nodes	891	50,0	12	1,3	905	49,7	10	1,1	1,22		Algorithm converged.	0,53	2,84	0,002		Algorithm converged.	-0,008	0,013		1,22		Algorithm converged.	0,53	2,81	0,6419		0,82		Algorithm converged.	0,36	1,89
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	10	1,7	0,10		Algorithm converged.	0,01	0,80	-0,015		Algorithm converged.	-0,026	-0,004		0,10		Algorithm converged.	0,01	0,81	0,0305		9,64		Algorithm converged.	1,24	75,03

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk		Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	ASTHMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	ATELECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)										
	BRONCHIECTASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 78.619475234 is greater than the limit of 0.0001. The convergence is questionable.	-0,083	0,080		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
	BRONCHOSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
	COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	DYSPHONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 112.62836143 is greater than the limit of 0.0001. The convergence is questionable.	-0,063	0,065		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	DYSPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4	0,82		Algorithm converged.	0,05	13,52	-0,004		Algorithm converged.	-0,064	0,056		0,82		Algorithm converged.	0,05	12,77	0,8896	-	1,21		Algorithm converged.	0,08	18,83
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2	0,51		Algorithm converged.	0,05	5,60	-0,001		Algorithm converged.	-0,005	0,003		0,51		Algorithm converged.	0,05	5,59	0,5798		1,97		Algorithm converged.	0,18	21,68

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	4	0,7	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	DYSPNOEA EXERTIONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	EPISTAXIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4	1,05		Algorithm converged.	0,07	16,82	0,000		Algorithm converged.	-0,010	0,011		1,05		Algorithm converged.	0,07	16,64	0,9744		0,96		Algorithm converged.	0,06	15,20
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	INTERSTITIAL LUNG DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	LUNG CONSOLIDATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	LUNG INFILTRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	NASAL OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	NASAL POLYPS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
	PLEURAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
	PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37	
	PNEUMOTHORAX	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95	
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003		1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	7	1,2	604	33,2	1	0,2	7,34		Algorithm converged.	0,90	59,85	0,010		Algorithm converged.	0,001	0,020	7,26		Algorithm converged.	0,90	58,86	0,0632		0,14		Algorithm converged.	0,02	1,12
	ACUTE FEBRILE NEUTROPHILIC DERMATOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DERMATITIS ACNEIFORM	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	DERMATITIS EXFOLIATIVE GENERALISED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131593 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	RASH MACULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
	SKIN ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE			NE		Algorithm converged.	NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	TOXIC SKIN ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131733 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE	
SURGICAL AND MEDICAL PROCEDURE	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE	
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE	
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE	

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	BREAST TUMOUR EXCISION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.99480022 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HOSPITALISATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009		0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	8	0,9	1,02		Algorithm converged.	0,38	2,72	0,000		Algorithm converged.	-0,009	0,009		1,02		Algorithm converged.	0,38	2,69	0,9750		0,98		Algorithm converged.	0,37	2,61
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	9	1,5	0,69		Algorithm converged.	0,24	1,95	-0,005		Algorithm converged.	-0,017	0,008		0,69		Algorithm converged.	0,25	1,93	0,4819		1,45		Algorithm converged.	0,52	4,04
	AXILLARY VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	DEEP VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk							Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72						
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005	1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37						
	EMBOLISM VENOUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE						
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE						
	HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE						

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 107.40965512 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,063	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1	1,02		Algorithm converged.	0,06	16,26	0,000		Algorithm converged.	-0,003	0,003	1,02		Algorithm converged.	0,06	16,21	0,9912		0,98		Algorithm converged.	0,06	15,72

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	3	0,5	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3	0,68		Algorithm converged.	0,11	4,06	-0,001		Algorithm converged.	-0,006	0,004		0,68		Algorithm converged.	0,11	4,04	0,6689		1,48		Algorithm converged.	0,25	8,82
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2	0,00		Algorithm converged.	0,00	NE	-0,002	*	WARNING: The relative Hessian convergence criterion of 73.994800 22 is greater than the limit of 0.0001. The convergence is questionable.	-0,081	0,077		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative e Risk	Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	LYMPHOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2	1,04		Algorithm converged.	0,06	16,63	0,000		Algorithm converged.	-0,005	0,005		1,04		Algorithm converged.	0,07	16,55	0,9791		0,96		Algorithm converged.	0,06	15,37
	PHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	SUBCLAVIAN VEIN THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	THROMBOPHLEBITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131 59 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108		NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO											PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	THROMBOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE			NE			NE	NE
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1	0,00		Algorithm converged.	0,00	NE	-0,001	*	WARNING: The relative Hessian convergence criterion of 114.12275857 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,065		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3	0,00		Algorithm converged.	0,00	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE		0,00		Algorithm converged.	0,00	NE	0,9999			>999		Algorithm converged.	0,00	NE
	VARICOSE VEIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE		NE			NE	NE	NE	-		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 119.89470733 is greater than the limit of 0.0001. The convergence is questionable.	-0,065	0,067	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	VENOUS THROMBOSIS LIMB	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0	NE		Algorithm converged.	NE	NE	0,001	*	WARNING: The relative Hessian convergence criterion of 116.14799773 is greater than the limit of 0.0001. The convergence is questionable.	-0,064	0,066	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0	NE		Algorithm converged.	NE	NE	0,020	*	WARNING: The relative Hessian convergence criterion of 44.368131448 is greater than the limit of 0.0001. The convergence is questionable.	-0,067	0,108	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsp.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsp_26d_10JAN2022_CHNS_AESAE_S1.xls
05MAY2022 18:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

All

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	14	0,8	1822	100,0	18	1,0
	ANAEMIA	n/a	1783	100,0	3	0,2	1822	100,0	3	0,2
	FEBRILE BONE MARROW APLASIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	FEBRILE NEUTROPENIA	n/a	1783	100,0	6	0,3	1822	100,0	5	0,3
	HAEMOLYTIC ANAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	LEUKOPENIA	n/a	1783	100,0	0	0,0	1822	100,0	6	0,3
	LYMPHADENOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	MYELOSUPPRESSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	NEUTROPENIA	n/a	1783	100,0	2	0,1	1822	100,0	5	0,3
	THROMBOCYTOPENIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2
CARDIAC DISORDER	-Total	n/a	1783	100,0	27	1,5	1822	100,0	27	1,5

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	ACUTE CORONARY SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ANGINA PECTORIS	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2
	ATRIAL FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	BUNDLE BRANCH BLOCK LEFT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	CARDIAC FAILURE	n/a	1783	100,0	22	1,2	1822	100,0	12	0,7
	CARDIAC FAILURE CONGESTIVE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CARDIAC VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DIASTOLIC DYSFUNCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	MITRAL VALVE INCOMPETENCE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	MYOCARDIAL ISCHAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PALPITATIONS	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
	PERICARDIAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	STRESS CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	SUPRAVENTRICULAR TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
EAR AND LABYRINTH DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	DEAFNESS BILATERAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	VERTIGO	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
EYE DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DIPLOPIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	42	2,4	1822	100,0	14	0,8
	ABDOMINAL DISTENSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	ABDOMINAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ABDOMINAL PAIN UPPER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	ANAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	APHTHOUS ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	COLITIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	CONSTIPATION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	DIARRHOEA	n/a	1783	100,0	26	1,5	1822	100,0	6	0,3
	DUODENAL ULCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	GASTRIC ULCER HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	GASTROINTESTINAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	GASTROINTESTINAL PERFORATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INTUSSUSCEPTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	LOWER GASTROINTESTINAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	NAUSEA	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1
	ORAL PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PROCTITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	RECTAL HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	SMALL INTESTINAL OBSTRUCTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	STOMATITIS	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0
	VOMITING	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	14	0,8	1822	100,0	20	1,1
	ASTHENIA	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2
	CHEST PAIN	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	CHILLS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	FATIGUE	n/a	1783	100,0	5	0,3	1822	100,0	7	0,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	GENERAL PHYSICAL HEALTH DETERIORATION	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2
	GENERALISED OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	MALAISE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	MUCOSAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	OEDEMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	OEDEMA PERIPHERAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PYREXIA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
HEPATOBILIARY DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	3	0,2
	HEPATIC FUNCTION ABNORMAL	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
	OCULAR ICTERUS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
IMMUNE SYSTEM DISORDER	-Total	n/a	1783	100,0	11	0,6	1822	100,0	5	0,3
	ANAPHYLACTIC REACTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	ANAPHYLACTIC SHOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DRUG HYPERSENSITIVITY	n/a	1783	100,0	4	0,2	1822	100,0	0	0,0
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	HYPERSENSITIVITY	n/a	1783	100,0	5	0,3	1822	100,0	3	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	17	1,0	1822	100,0	15	0,8
	BRONCHITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	CELLULITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CLOSTRIDIUM DIFFICILE INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	CONJUNCTIVITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DEVICE RELATED SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DIVERTICULITIS INTESTINAL PERFORATED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ERYSIPELAS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	FOLLICULITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	GASTROENTERITIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	GROIN ABSCESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INFECTED LYMPHOCELE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	LOCALISED INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	LOWER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PARONYCHIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PNEUMONIA	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PNEUMONIA ASPIRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PNEUMONIA BACTERIAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PSEUDOMONAL BACTERAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PSEUDOMONAS INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	RESPIRATORY TRACT INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	SEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	SKIN INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	URINARY TRACT INFECTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	UROSEPSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	VIRAL INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	VIRAL UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	WOUND ABSCESS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	7	0,4
	CONTUSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	FEMORAL NECK FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	INFUSION RELATED REACTION	n/a	1783	100,0	0	0,0	1822	100,0	4	0,2
	NAIL INJURY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
INVESTIGATION	-Total	n/a	1783	100,0	42	2,4	1822	100,0	64	3,5
	ALANINE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	8	0,4
	ASPARTATE AMINOTRANSFERASE INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	6	0,3
	BLOOD ALKALINE PHOSPHATASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	BLOOD BILIRUBIN INCREASED	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	BLOOD CREATININE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	BLOOD LACTATE DEHYDROGENASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	EJECTION FRACTION DECREASED	n/a	1783	100,0	32	1,8	1822	100,0	47	2,6
	FORCED EXPIRATORY VOLUME DECREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	NEUTROPHIL COUNT DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
	PLATELET COUNT DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	TRANSAMINASES INCREASED	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	WEIGHT DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	WHITE BLOOD CELL COUNT DECREASED	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	8	0,4	1822	100,0	3	0,2
	CELL DEATH	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DECREASED APPETITE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	DEHYDRATION	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0
	FLUID RETENTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	HYPOCALCAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	HYPOKALAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	HYPOMAGNESAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	HYPOPHOSPHATAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	TETANY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	5	0,3
	ARTHRALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	MUSCULOSKELETAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MYALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	PAIN IN EXTREMITY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2
	ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ADENOCARCINOMA PANCREAS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	GASTRIC NEOPLASM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	SMALL CELL LUNG CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	50	2,8	1822	100,0	38	2,1
	ATAXIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	CEREBRAL HAEMORRHAGE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	CEREBRAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CEREBROVASCULAR ACCIDENT	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DEMENTIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	HEADACHE	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	INTRACRANIAL ANEURYSM	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	LETHARGY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	NEURALGIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	NEUROPATHY PERIPHERAL	n/a	1783	100,0	13	0,7	1822	100,0	9	0,5
	NEUROTOXICITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PARAESTHESIA	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3
	PERIPHERAL SENSORY NEUROPATHY	n/a	1783	100,0	15	0,8	1822	100,0	17	0,9
	POLYNEUROPATHY	n/a	1783	100,0	5	0,3	1822	100,0	2	0,1
	SUBARACHNOID HAEMORRHAGE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	SYNCOPE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	TASTE DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	TRIGEMINAL NEURALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
PSYCHIATRIC DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	6	0,3
	ANXIETY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CONFUSIONAL STATE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DEPRESSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	INSOMNIA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	MAJOR DEPRESSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	MENTAL DISORDER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
RENAL AND URINARY DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	3	0,2
	ACUTE KIDNEY INJURY	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
	RENAL FAILURE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	URINARY INCONTINENCE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	PELVIC CYST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	VULVOVAGINAL INFLAMMATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	7	0,4	1822	100,0	14	0,8
	BRONCHOSPASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	COUGH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	DYSPNOEA	n/a	1783	100,0	0	0,0	1822	100,0	6	0,3
	DYSPNOEA EXERTIONAL	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INTERSTITIAL LUNG DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	LUNG CONSOLIDATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	LUNG INFILTRATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	OROPHARYNGEAL PAIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PNEUMONITIS	n/a	1783	100,0	3	0,2	1822	100,0	2	0,1
	PULMONARY EMBOLISM	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	PULMONARY FIBROSIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	n/a	1783	100,0	22	1,2	1822	100,0	10	0,5
	ALOPECIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	ANGIOEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DERMATITIS EXFOLIATIVE GENERALISED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DRUG ERUPTION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	DRY SKIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	ERYTHEMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	EXFOLIATIVE RASH	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	NAIL TOXICITY	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	ONYCHOLYSIS	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	n/a	1783	100,0	4	0,2	1822	100,0	2	0,1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PRURITUS	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
	PSORIASIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	PURPURA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	RASH	n/a	1783	100,0	6	0,3	1822	100,0	1	<0.1
	RASH MACULO-PAPULAR	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	URTICARIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
VASCULAR DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
	HAEMATOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	HYPERTENSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	HYPOTENSION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AEDISC_S1.xls
04MAY2022 9:45

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Age II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	< 65	1564	87,7	8	0,5	1601	87,9	12	0,7
		>= 65	219	12,3	6	2,7	221	12,1	6	2,7
	ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	2	0,9	221	12,1	2	0,9
	FEBRILE BONE MARROW APLASIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	FEBRILE NEUTROPENIA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2
		>= 65	219	12,3	4	1,8	221	12,1	2	0,9
	HAEMOLYTIC ANAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	LEUKOPENIA	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9
	LYMPHADENOPATHY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MYELOSUPPRESSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	NEUTROPENIA	< 65	1564	87,7	2	0,1	1601	87,9	3	0,2
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9
	THROMBOCYTOPENIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4
CARDIAC DISORDER	-Total	< 65	1564	87,7	19	1,2	1601	87,9	20	1,2
		>= 65	219	12,3	8	3,7	221	12,1	7	3,2
	ACUTE CORONARY SYNDROME	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ACUTE MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	ANGINA PECTORIS	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	ATRIAL FIBRILLATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	BUNDLE BRANCH BLOCK LEFT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CARDIAC FAILURE	< 65	1564	87,7	14	0,9	1601	87,9	9	0,6
		>= 65	219	12,3	8	3,7	221	12,1	3	1,4
	CARDIAC FAILURE CONGESTIVE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	CARDIAC VALVE DISEASE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	DIASTOLIC DYSFUNCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MITRAL VALVE INCOMPETENCE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MYOCARDIAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	MYOCARDIAL ISCHAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PALPITATIONS	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PERICARDIAL EFFUSION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	STRESS CARDIOMYOPATHY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	SUPRAVENTRICULAR TACHYCARDIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	VENTRICULAR ARRHYTHMIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
EAR AND LABYRINTH DISORDER	-Total	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	DEAFNESS BILATERAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	VERTIGO	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
EYE DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DIPLOPIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
GASTROINTESTINAL DISORDER	-Total	< 65	1564	87,7	27	1,7	1601	87,9	9	0,6
		>= 65	219	12,3	15	6,8	221	12,1	5	2,3
	ABDOMINAL DISTENSION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ABDOMINAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ABDOMINAL PAIN UPPER	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ANAL INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	APHTHOUS ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	COLITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	CONSTIPATION	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DIARRHOEA	< 65	1564	87,7	14	0,9	1601	87,9	2	0,1
		>= 65	219	12,3	12	5,5	221	12,1	4	1,8
	DUODENAL ULCER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	GASTRIC ULCER HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	GASTROINTESTINAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	GASTROINTESTINAL PERFORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	INTUSSUSCEPTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	LOWER GASTROINTESTINAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	NAUSEA	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	ORAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	PROCTITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	RECTAL HAEMORRHAGE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	SMALL INTESTINAL OBSTRUCTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	STOMATITIS	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	VOMITING	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	< 65	1564	87,7	6	0,4	1601	87,9	11	0,7
		>= 65	219	12,3	8	3,7	221	12,1	9	4,1
	ASTHENIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9
	CHEST PAIN	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CHILLS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	FATIGUE	< 65	1564	87,7	1	<0.1	1601	87,9	3	0,2
		>= 65	219	12,3	4	1,8	221	12,1	4	1,8
	GENERAL PHYSICAL HEALTH DETERIORATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9
	GENERALISED OEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MALAISE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	MUCOSAL INFLAMMATION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	OEDEMA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	OEDEMA PERIPHERAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	PYREXIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
HEPATOBILIARY DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	HEPATIC FUNCTION ABNORMAL	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	OCULAR ICTERUS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
IMMUNE SYSTEM DISORDER	-Total	< 65	1564	87,7	10	0,6	1601	87,9	4	0,2
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
	ANAPHYLACTIC REACTION	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ANAPHYLACTIC SHOCK	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DRUG HYPERSENSITIVITY	< 65	1564	87,7	4	0,3	1601	87,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HYPERSENSITIVITY	< 65	1564	87,7	4	0,3	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
INFECTIONS AND INFESTATION	-Total	< 65	1564	87,7	10	0,6	1601	87,9	12	0,7
		>= 65	219	12,3	7	3,2	221	12,1	3	1,4
	BRONCHITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	CELLULITIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CLOSTRIDIUM DIFFICILE INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CONJUNCTIVITIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	DEVICE RELATED SEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	DIVERTICULITIS INTESTINAL PERFORATED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ERYSIPELAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	FOLLICULITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	GASTROENTERITIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	GROIN ABSCESS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	INFECTED LYMPHOCELE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	LOCALISED INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	LOWER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PARONYCHIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PNEUMONIA	< 65	1564	87,7	1	<0.1	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
	PNEUMONIA ASPIRATION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PNEUMONIA BACTERIAL	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PSEUDOMONAL BACTERAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PSEUDOMONAS INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	RESPIRATORY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	SEPSIS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	SKIN INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	URINARY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	UROSEPSIS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	VIRAL INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	VIRAL UPPER RESPIRATORY TRACT INFECTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	WOUND ABSCESS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	7	0,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CONTUSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	FEMORAL NECK FRACTURE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	INFUSION RELATED REACTION	< 65	1564	87,7	0	0,0	1601	87,9	4	0,2
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	NAIL INJURY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
INVESTIGATION	-Total	< 65	1564	87,7	33	2,1	1601	87,9	53	3,3
		>= 65	219	12,3	9	4,1	221	12,1	11	5,0
	ALANINE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	1	<0.1	1601	87,9	8	0,5
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	1564	87,7	2	0,1	1601	87,9	6	0,4
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	BLOOD BILIRUBIN INCREASED	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	BLOOD CREATININE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	EJECTION FRACTION DECREASED	< 65	1564	87,7	25	1,6	1601	87,9	40	2,5
		>= 65	219	12,3	7	3,2	221	12,1	7	3,2
	FORCED EXPIRATORY VOLUME DECREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	NEUTROPHIL COUNT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9
	PLATELET COUNT DECREASED	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	TRANSAMINASES INCREASED	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	WEIGHT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	WHITE BLOOD CELL COUNT DECREASED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
METABOLISM AND NUTRITION DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	2	0,1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	3	1,4	221	12,1	1	0,5
	CELL DEATH	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DECREASED APPETITE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DEHYDRATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	3	1,4	221	12,1	0	0,0
	FLUID RETENTION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	HYPOCALCAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HYPOKALAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HYPOMAGNESAEMIA	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HYPOPHOSPHATAEMIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	TETANY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	< 65	1564	87,7	3	0,2	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	3	1,4
	ARTHRALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MUSCULOSKELETAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	3	1,4
	MYALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PAIN IN EXTREMITY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	< 65	1564	87,7	2	0,1	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	2	0,9
	ACUTE MYELOID LEUKAEMIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ADENOCARCINOMA PANCREAS	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	GASTRIC NEOPLASM	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	LUNG NEOPLASM MALIGNANT	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MENINGIOMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	SMALL CELL LUNG CANCER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
NERVOUS SYSTEM DISORDER	-Total	< 65	1564	87,7	34	2,2	1601	87,9	26	1,6

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	16	7,3	221	12,1	12	5,4
	ATAXIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	CEREBRAL HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	2	0,9	221	12,1	0	0,0
	CEREBRAL INFARCTION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CEREBROVASCULAR ACCIDENT	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	DEMENTIA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	HEADACHE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	INTRACRANIAL ANEURYSM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	LETHARGY	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	NEURALGIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	NEUROPATHY PERIPHERAL	< 65	1564	87,7	10	0,6	1601	87,9	6	0,4
		>= 65	219	12,3	3	1,4	221	12,1	3	1,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	NEUROTOXICITY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PARAESTHESIA	< 65	1564	87,7	8	0,5	1601	87,9	5	0,3
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	PERIPHERAL SENSORY NEUROPATHY	< 65	1564	87,7	10	0,6	1601	87,9	11	0,7
		>= 65	219	12,3	5	2,3	221	12,1	6	2,7
	POLYNEUROPATHY	< 65	1564	87,7	3	0,2	1601	87,9	1	<0.1
		>= 65	219	12,3	2	0,9	221	12,1	1	0,5
	SUBARACHNOID HAEMORRHAGE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	SYNCOPE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	TASTE DISORDER	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	TRIGEMINAL NEURALGIA	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
PSYCHIATRIC DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	5	0,3
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	ANXIETY	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	CONFUSIONAL STATE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	DEPRESSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	INSOMNIA	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	MAJOR DEPRESSION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	MENTAL DISORDER	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
RENAL AND URINARY DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9
	ACUTE KIDNEY INJURY	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
	RENAL FAILURE	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	URINARY INCONTINENCE	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	PELVIC CYST	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	VULVOVAGINAL INFLAMMATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	< 65	1564	87,7	5	0,3	1601	87,9	10	0,6
		>= 65	219	12,3	2	0,9	221	12,1	4	1,8
	BRONCHOSPASM	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	COUGH	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DYSPNOEA	< 65	1564	87,7	0	0,0	1601	87,9	5	0,3
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	DYSPNOEA EXERTIONAL	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	INTERSTITIAL LUNG DISEASE	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	LUNG CONSOLIDATION	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	LUNG INFILTRATION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	OROPHARYNGEAL PAIN	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PNEUMONITIS	< 65	1564	87,7	2	0,1	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
	PULMONARY EMBOLISM	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	PULMONARY FIBROSIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	< 65	1564	87,7	19	1,2	1601	87,9	4	0,2
		>= 65	219	12,3	3	1,4	221	12,1	6	2,7
	ALOPECIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ANGIOEDEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DERMATITIS EXFOLIATIVE GENERALISED	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DRUG ERUPTION	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	DRY SKIN	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	ERYTHEMA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	EXFOLIATIVE RASH	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5
	NAIL TOXICITY	< 65	1564	87,7	2	0,1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	ONYCHOLYSIS	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	1	0,5

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	< 65	1564	87,7	3	0,2	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	2	0,9
	PRURITUS	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	1	0,5
	PSORIASIS	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	PURPURA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	RASH	< 65	1564	87,7	5	0,3	1601	87,9	1	<0.1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	RASH MACULO-PAPULAR	< 65	1564	87,7	1	<0.1	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	URTICARIA	< 65	1564	87,7	1	<0.1	1601	87,9	0	0,0
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
VASCULAR DISORDER	-Total	< 65	1564	87,7	0	0,0	1601	87,9	2	0,1
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	HAEMATOMA	< 65	1564	87,7	0	0,0	1601	87,9	0	0,0
		>= 65	219	12,3	1	0,5	221	12,1	0	0,0
	HYPERTENSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0
	HYPOTENSION	< 65	1564	87,7	0	0,0	1601	87,9	1	<0.1
		>= 65	219	12,3	0	0,0	221	12,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AEDISC_S1.xls
04MAY2022 9:45

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Geographical region II

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8
		Western Europe	814	45,7	5	0,6	824	45,2	9	1,1
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8
		Latin America	42	2,4	2	4,8	45	2,5	1	2,2
		Other	183	10,3	2	1,1	184	10,1	2	1,1
	ANAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	FEBRILE BONE MARROW APLASIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	FEBRILE NEUTROPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4
		Asia Pacific	482	27,0	4	0,8	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LEUKOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	2	1,1
	LYMPHADENOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MYELOSUPPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NEUTROPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	2	1,1
	THROMBOCYTOPENIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
CARDIAC DISORDER	-Total	USA/Canada	262	14,7	6	2,3	252	13,8	4	1,6
		Western Europe	814	45,7	16	2,0	824	45,2	14	1,7
		Asia Pacific	482	27,0	3	0,6	517	28,4	5	1,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	2	1,1	184	10,1	3	1,6
	ACUTE CORONARY SYNDROME	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ACUTE MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ANGINA PECTORIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	2	1,1
	ATRIAL FIBRILLATION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	BUNDLE BRANCH BLOCK LEFT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CARDIAC FAILURE	USA/Canada	262	14,7	5	1,9	252	13,8	2	0,8
		Western Europe	814	45,7	14	1,7	824	45,2	8	1,0
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	CARDIAC FAILURE CONGESTIVE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CARDIAC VALVE DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DIASTOLIC DYSFUNCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MITRAL VALVE INCOMPETENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MYOCARDIAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MYOCARDIAL ISCHAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PALPITATIONS	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PERICARDIAL EFFUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	STRESS CARDIOMYOPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	SUPRAVENTRICULAR TACHYCARDIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	VENTRICULAR ARRHYTHMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
EAR AND LABYRINTH DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	DEAFNESS BILATERAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	VERTIGO	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
EYE DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DIPLOPIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
GASTROINTESTINAL DISORDER	-Total	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2
		Western Europe	814	45,7	25	3,1	824	45,2	8	1,0
		Asia Pacific	482	27,0	10	2,1	517	28,4	3	0,6
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	3	1,6	184	10,1	0	0,0
	ABDOMINAL DISTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ABDOMINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ABDOMINAL PAIN UPPER	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ANAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	APHTHOUS ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	COLITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CONSTIPATION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DIARRHOEA	USA/Canada	262	14,7	3	1,1	252	13,8	1	0,4
		Western Europe	814	45,7	18	2,2	824	45,2	4	0,5
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	2	1,1	184	10,1	0	0,0
	DUODENAL ULCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	GASTRIC ULCER HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GASTROINTESTINAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GASTROINTESTINAL PERFORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	INTUSSUSCEPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LOWER GASTROINTESTINAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NAUSEA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ORAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	PROCTITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	RECTAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SMALL INTESTINAL OBSTRUCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	STOMATITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	VOMITING	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	3	0,6	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8
		Western Europe	814	45,7	9	1,1	824	45,2	15	1,8
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	3	1,6	184	10,1	2	1,1
	ASTHENIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CHEST PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	CHILLS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	FATIGUE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	3	0,4	824	45,2	5	0,6
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	2	1,1	184	10,1	2	1,1
	GENERAL PHYSICAL HEALTH DETERIORATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GENERALISED OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MALAISE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MUCOSAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	OEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	OEDEMA PERIPHERAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PYREXIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	2	0,2	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
HEPATOBILIARY DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HEPATIC FUNCTION ABNORMAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	OCULAR ICTERUS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
IMMUNE SYSTEM DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4
		Western Europe	814	45,7	6	0,7	824	45,2	2	0,2
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	1	0,5
	ANAPHYLACTIC REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ANAPHYLACTIC SHOCK	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DRUG HYPERSENSITIVITY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPERSENSITIVITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	3	0,4	824	45,2	1	0,1
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	1	0,5
INFECTIONS AND INFESTATION	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	2	0,8
		Western Europe	814	45,7	11	1,4	824	45,2	8	1,0
		Asia Pacific	482	27,0	2	0,4	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	1	0,5	184	10,1	2	1,1
	BRONCHITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CELLULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CLOSTRIDIUM DIFFICILE INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CONJUNCTIVITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DEVICE RELATED SEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DIVERTICULITIS INTESTINAL PERFORATED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ERYSIPELAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	FOLLICULITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GASTROENTERITIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GROIN ABSCESS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	INFECTED LYMPHOCELE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	LOCALISED INFECTION	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LOWER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PARONYCHIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PNEUMONIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	2	0,2	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	PNEUMONIA ASPIRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PNEUMONIA BACTERIAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PSEUDOMONAL BACTERAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PSEUDOMONAS INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SEPSIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SKIN INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	URINARY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	UROSEPSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	VIRAL INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	VIRAL UPPER RESPIRATORY TRACT INFECTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	WOUND ABSCESS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	4	0,5
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	CONTUSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	FEMORAL NECK FRACTURE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	INFUSION RELATED REACTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NAIL INJURY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
INVESTIGATION	-Total	USA/Canada	262	14,7	12	4,6	252	13,8	9	3,6
		Western Europe	814	45,7	21	2,6	824	45,2	40	4,9
		Asia Pacific	482	27,0	7	1,5	517	28,4	9	1,7

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Latin America	42	2,4	0	0,0	45	2,5	2	4,4
		Other	183	10,3	2	1,1	184	10,1	4	2,2
	ALANINE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	1	0,2	517	28,4	4	0,8
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	ASPARTATE AMINOTRANSFERASE INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	BLOOD ALKALINE PHOSPHATASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	BLOOD BILIRUBIN INCREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	BLOOD CREATININE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	BLOOD LACTATE DEHYDROGENASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	EJECTION FRACTION DECREASED	USA/Canada	262	14,7	9	3,4	252	13,8	6	2,4
		Western Europe	814	45,7	17	2,1	824	45,2	34	4,1
		Asia Pacific	482	27,0	4	0,8	517	28,4	4	0,8
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	2	1,1	184	10,1	3	1,6
	FORCED EXPIRATORY VOLUME DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NEUTROPHIL COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PLATELET COUNT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	TRANSAMINASES INCREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	WEIGHT DECREASED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	WHITE BLOOD CELL COUNT DECREASED	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
METABOLISM AND NUTRITION DISORDER	-Total	USA/Canada	262	14,7	5	1,9	252	13,8	1	0,4
		Western Europe	814	45,7	3	0,4	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	2	0,4
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CELL DEATH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DECREASED APPETITE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DEHYDRATION	USA/Canada	262	14,7	3	1,1	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	FLUID RETENTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPOCALCAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPOKALAEMIA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPOMAGNESAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPOPHOSPHATAEMIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	TETANY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	ARTHRALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MUSCULOSKELETAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	MYALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PAIN IN EXTREMITY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	2	0,2	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ACUTE MYELOID LEUKAEMIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ADENOCARCINOMA PANCREAS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	GASTRIC NEOPLASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LUNG NEOPLASM MALIGNANT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MENINGIOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SMALL CELL LUNG CANCER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
NERVOUS SYSTEM DISORDER	-Total	USA/Canada	262	14,7	13	5,0	252	13,8	6	2,4
		Western Europe	814	45,7	25	3,1	824	45,2	20	2,4
		Asia Pacific	482	27,0	9	1,9	517	28,4	9	1,7
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	3	1,6	184	10,1	3	1,6
	ATAXIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CEREBRAL HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CEREBRAL INFARCTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CEREBROVASCULAR ACCIDENT	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DEMENTIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HEADACHE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	INTRACRANIAL ANEURYSM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LETHARGY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NEURALGIA	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NEUROPATHY PERIPHERAL	USA/Canada	262	14,7	4	1,5	252	13,8	1	0,4
		Western Europe	814	45,7	6	0,7	824	45,2	2	0,2
		Asia Pacific	482	27,0	3	0,6	517	28,4	3	0,6
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	3	1,6
	NEUROTOXICITY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PARAESTHESIA	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4
		Western Europe	814	45,7	3	0,4	824	45,2	4	0,5
		Asia Pacific	482	27,0	1	0,2	517	28,4	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	2	1,1	184	10,1	0	0,0
	PERIPHERAL SENSORY NEUROPATHY	USA/Canada	262	14,7	4	1,5	252	13,8	3	1,2
		Western Europe	814	45,7	7	0,9	824	45,2	10	1,2
		Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	POLYNEUROPATHY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	5	0,6	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SUBARACHNOID HAEMORRHAGE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	SYNCOPE	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	TASTE DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	TRIGEMINAL NEURALGIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
PSYCHIATRIC DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ANXIETY	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	CONFUSIONAL STATE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	INSOMNIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MAJOR DEPRESSION	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	MENTAL DISORDER	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
RENAL AND URINARY DISORDER	-Total	USA/Canada	262	14,7	2	0,8	252	13,8	2	0,8
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ACUTE KIDNEY INJURY	USA/Canada	262	14,7	2	0,8	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	RENAL FAILURE	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	URINARY INCONTINENCE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	0	0,0
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	2	0,2	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PELVIC CYST	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	VULVOVAGINAL INFLAMMATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	USA/Canada	262	14,7	1	0,4	252	13,8	2	0,8
		Western Europe	814	45,7	3	0,4	824	45,2	8	1,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	2	0,4
		Latin America	42	2,4	1	2,4	45	2,5	1	2,2
		Other	183	10,3	1	0,5	184	10,1	1	0,5
	BRONCHOSPASM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	COUGH	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DYSPNOEA	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8
		Western Europe	814	45,7	0	0,0	824	45,2	3	0,4
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	1	2,2
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DYSPNOEA EXERTIONAL	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	1	0,5
	INTERSTITIAL LUNG DISEASE	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LUNG CONSOLIDATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	LUNG INFILTRATION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	OROPHARYNGEAL PAIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PNEUMONITIS	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	1	2,4	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PULMONARY EMBOLISM	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PULMONARY FIBROSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	USA/Canada	262	14,7	3	1,1	252	13,8	3	1,2
		Western Europe	814	45,7	14	1,7	824	45,2	6	0,7
		Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	3	1,6	184	10,1	0	0,0
	ALOPECIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ANGIOEDEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	DERMATITIS EXFOLIATIVE GENERALISED	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DRUG ERUPTION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	DRY SKIN	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ERYTHEMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	EXFOLIATIVE RASH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	NAIL TOXICITY	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	ONYCHOLYSIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	USA/Canada	262	14,7	1	0,4	252	13,8	0	0,0
		Western Europe	814	45,7	3	0,4	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	PRURITUS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	1	0,2
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	1	0,5	184	10,1	0	0,0
	PSORIASIS	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PURPURA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	RASH	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4
		Western Europe	814	45,7	5	0,6	824	45,2	0	0,0
		Asia Pacific	482	27,0	1	0,2	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	RASH MACULO-PAPULAR	USA/Canada	262	14,7	1	0,4	252	13,8	1	0,4
		Western Europe	814	45,7	0	0,0	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	URTICARIA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
VASCULAR DISORDER	-Total	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	2	0,2
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HAEMATOMA	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	1	0,1	824	45,2	0	0,0
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPERTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0
	HYPOTENSION	USA/Canada	262	14,7	0	0,0	252	13,8	0	0,0
		Western Europe	814	45,7	0	0,0	824	45,2	1	0,1
		Asia Pacific	482	27,0	0	0,0	517	28,4	0	0,0
		Latin America	42	2,4	0	0,0	45	2,5	0	0,0
		Other	183	10,3	0	0,0	184	10,1	0	0,0

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AEDISC_S1.xls
04MAY2022 9:45

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

Subgroup: Nodal status and tumor size

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	9	1,0
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	6	1,0
	ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	FEBRILE BONE MARROW APLASIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	FEBRILE NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	4	0,4
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	0	0,0
	HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	LEUKOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	LYMPHADENOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	MICROANGIOPATHIC HAEMOLYTIC ANAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MYELOSUPPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	NEUTROPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3
	THROMBOCYTOPENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3
CARDIAC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	4	1,5
		1-3 positive nodes	891	50,0	9	1,0	905	49,7	16	1,8

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 4 positive nodes	582	32,6	15	2,6	604	33,2	7	1,2
	ACUTE CORONARY SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	ACUTE MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ANGINA PECTORIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ATRIAL FIBRILLATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	BUNDLE BRANCH BLOCK LEFT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	CARDIAC FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8
		>= 4 positive nodes	582	32,6	12	2,1	604	33,2	4	0,7
	CARDIAC FAILURE CONGESTIVE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	CARDIAC VALVE DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	DIASTOLIC DYSFUNCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MITRAL VALVE INCOMPETENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MYOCARDIAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MYOCARDIAL ISCHAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	PALPITATIONS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	PERICARDIAL EFFUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	STRESS CARDIOMYOPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	SUPRAVENTRICULAR TACHYCARDIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	VENTRICULAR ARRHYTHMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2
EAR AND LABYRINTH DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	DEAFNESS BILATERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	VERTIGO	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
EYE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DIPLOPIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
GASTROINTESTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	7	0,8
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	5	0,8
	ABDOMINAL DISTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ABDOMINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ABDOMINAL PAIN UPPER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	ANAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	APHTHOUS ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	COLITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	CONSTIPATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DIARRHOEA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	13	1,5	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	9	1,5	604	33,2	3	0,5
	DUODENAL ULCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	GASTRIC ULCER HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	GASTROINTESTINAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	GASTROINTESTINAL PERFORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	INTUSSUSCEPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	LOWER GASTROINTESTINAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	NAUSEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	ORAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PROCTITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	RECTAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2
	SMALL INTESTINAL OBSTRUCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	STOMATITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	VOMITING	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	4	1,5
		1-3 positive nodes	891	50,0	7	0,8	905	49,7	9	1,0
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	7	1,2
	ASTHENIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	CHEST PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	CHILLS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	FATIGUE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5
	GENERAL PHYSICAL HEALTH DETERIORATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3
	GENERALISED OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MALAISE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MUCOSAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	OEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	OEDEMA PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	PYREXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2
HEPATOBILIARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	HEPATIC FUNCTION ABNORMAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	OCULAR ICTERUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
IMMUNE SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	6	0,7	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2
	ANAPHYLACTIC REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	ANAPHYLACTIC SHOCK	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DRUG HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	HYPERSENSITIVITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
INFECTIONS AND INFESTATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	3	1,1
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	6	0,7
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	6	1,0
	BRONCHITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	CELLULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	CLOSTRIDIUM DIFFICILE INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	CONJUNCTIVITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DEVICE RELATED SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DIVERTICULITIS INTESTINAL PERFORATED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ERYSIPELAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	FOLLICULITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	GASTROENTERITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	GROIN ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	INFECTED LYMPHOCELE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	LOCALISED INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	LOWER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PARONYCHIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PNEUMONIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	PNEUMONIA ASPIRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PNEUMONIA BACTERIAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PSEUDOMONAL BACTERAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PSEUDOMONAS INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	SEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	SKIN INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	URINARY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	UROSEPSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	VIRAL INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	VIRAL UPPER RESPIRATORY TRACT INFECTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	WOUND ABSCESS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	4	0,4
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	CONTUSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	FEMORAL NECK FRACTURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	INFUSION RELATED REACTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	NAIL INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
INVESTIGATION	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	6	2,2
		1-3 positive nodes	891	50,0	23	2,6	905	49,7	34	3,8
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	23	3,8
	ALANINE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	4	0,7

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	ASPARTATE AMINOTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	3	0,5
	BLOOD ALKALINE PHOSPHATASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3
	BLOOD BILIRUBIN INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	BLOOD CREATININE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	BLOOD LACTATE DEHYDROGENASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	EJECTION FRACTION DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	4	1,5
		1-3 positive nodes	891	50,0	18	2,0	905	49,7	27	3,0
		>= 4 positive nodes	582	32,6	11	1,9	604	33,2	16	2,6

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	FORCED EXPIRATORY VOLUME DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	NEUTROPHIL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2
	PLATELET COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	TRANSAMINASES INCREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	WEIGHT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	WHITE BLOOD CELL COUNT DECREASED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
METABOLISM AND NUTRITION DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	5	0,6	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	3	0,5	604	33,2	1	0,2
	CELL DEATH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DECREASED APPETITE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DEHYDRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	FLUID RETENTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	HYPOCALCAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	HYPOKALAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	1	0,2
	HYPOMAGNESAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2
	HYPOPHOSPHATAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	TETANY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2
	ARTHRALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MUSCULOSKELETAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MYALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	PAIN IN EXTREMITY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3
	ACUTE MYELOID LEUKAEMIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	ADENOCARCINOMA PANCREAS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	GASTRIC NEOPLASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	LUNG NEOPLASM MALIGNANT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MENINGIOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	SMALL CELL LUNG CANCER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
NERVOUS SYSTEM DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	2	4,8
		0 positive nodes, tumor > 1 cm	259	14,5	9	3,5	271	14,9	11	4,1
		1-3 positive nodes	891	50,0	26	2,9	905	49,7	17	1,9
		>= 4 positive nodes	582	32,6	14	2,4	604	33,2	8	1,3
	ATAXIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	AUTONOMIC NERVOUS SYSTEM IMBALANCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	CEREBRAL HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	CEREBRAL INFARCTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	CEREBROVASCULAR ACCIDENT	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	DEMENTIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	HEADACHE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	INTRACRANIAL ANEURYSM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	LETHARGY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	NEUROPATHY PERIPHERAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	5	0,6
		>= 4 positive nodes	582	32,6	4	0,7	604	33,2	2	0,3
	NEUROTOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PARAESTHESIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	1	2,4
		0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	2	0,3
	PERIPHERAL SENSORY NEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	1	2,4
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	6	2,2
		1-3 positive nodes	891	50,0	8	0,9	905	49,7	7	0,8
		>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5
	POLYNEUROPATHY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	4	0,4	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	1	0,2
	SUBARACHNOID HAEMORRHAGE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	SYNCOPE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	TASTE DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	TRIGEMINAL NEURALGIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
PSYCHIATRIC DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	4	0,4
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3
	ANXIETY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	CONFUSIONAL STATE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	INSOMNIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	MAJOR DEPRESSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	MENTAL DISORDER	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
RENAL AND URINARY DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	ACUTE KIDNEY INJURY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	RENAL FAILURE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	URINARY INCONTINENCE	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
REPRODUCTIVE SYSTEM AND BREAST DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	PELVIC CYST	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	VULVOVAGINAL INFLAMMATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	5	1,8
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	6	0,7
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	3	0,5
	BRONCHOSPASM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	COUGH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DYSPNOEA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	3	0,3
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	2	0,3
	DYSPNOEA EXERTIONAL	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	INTERSTITIAL LUNG DISEASE	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	LUNG CONSOLIDATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	LUNG INFILTRATION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	OROPHARYNGEAL PAIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PNEUMONITIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	PULMONARY EMBOLISM	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	1	0,2
	PULMONARY FIBROSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
SKIN AND SUBCUTANEOUS TISSUE DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	5	1,8
		1-3 positive nodes	891	50,0	10	1,1	905	49,7	5	0,6
		>= 4 positive nodes	582	32,6	6	1,0	604	33,2	0	0,0
	ALOPECIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ANGIOEDEMA	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DERMATITIS EXFOLIATIVE GENERALISED	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	DRUG ERUPTION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	DRY SKIN	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
	ERYTHEMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	EXFOLIATIVE RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	NAIL TOXICITY	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	ONYCHOLYSIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	2	0,2	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	PRURITUS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	PSORIASIS	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	PURPURA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	RASH	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	3	0,3	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	2	0,3	604	33,2	0	0,0
	RASH MACULO-PAPULAR	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	1	0,4
		1-3 positive nodes	891	50,0	1	0,1	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	URTICARIA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
VASCULAR DISORDER	-Total	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	2	0,2
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	HAEMATOMA	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	0	0,0
		>= 4 positive nodes	582	32,6	1	0,2	604	33,2	0	0,0
	HYPERTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1

			PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
			Patients		Patients with Event		Patients		Patients with Event	
SOC	PT	Level	n	%	n	%	n	%	n	%
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0
	HYPOTENSION	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0
		0 positive nodes, tumor > 1 cm	259	14,5	0	0,0	271	14,9	0	0,0
		1-3 positive nodes	891	50,0	0	0,0	905	49,7	1	0,1
		>= 4 positive nodes	582	32,6	0	0,0	604	33,2	0	0,0

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AEDISC_S1.xls
04MAY2022 9:45

Verträglichkeit (Datenschnitt: 10.01.2022)

Responder Analysen

Spezifische Verträglichkeit

Unstratifiziert + Subgruppen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Congestive heart failure / left ventricular dysfunction (SAEs)
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)	Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	33	1,9	1822	100,0	19	1,0	1,79		Algorithm converged.	1,01	3,16	0,008		Algorithm converged.	0,000	0,016	1,77		Algorithm converged.	1,01	3,11	0,0449		0,56		Algorithm converged.	0,32	0,99
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
	1-3 positive nodes	891	50,0	14	1,6	905	49,7	11	1,2	1,30		Algorithm converged.	0,59	2,87	0,004		Algorithm converged.	-0,007	0,014	1,29		Algorithm converged.	0,59	2,83	0,5211		0,77		Algorithm converged.	0,35	1,69
	>= 4 positive nodes	582	32,6	15	2,6	604	33,2	7	1,2	2,26		Algorithm converged.	0,91	5,57	0,014		Algorithm converged.	-0,001	0,030	2,22		Algorithm converged.	0,91	5,41	0,0784		0,45		Algorithm converged.	0,18	1,09
Geographical region II	USA/Canada	262	14,7	7	2,7	252	13,8	3	1,2	2,28		Algorithm converged.	0,58	8,91	0,015		Algorithm converged.	-0,009	0,038	2,24		Algorithm converged.	0,59	8,58	0,2375	-	0,45		Algorithm converged.	0,12	1,70
	Western Europe	814	45,7	18	2,2	824	45,2	12	1,5	1,53		Algorithm converged.	0,73	3,20	0,008		Algorithm converged.	-0,005	0,021	1,52		Algorithm converged.	0,74	3,13	0,2582		0,66		Algorithm converged.	0,32	1,36
	Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013	1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
	Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Other	183	10,3	4	2,2	184	10,1	1	0,5	4,09		Algorithm converged.	0,45	36,94	0,016		Algorithm converged.	-0,007	0,040	4,02		Algorithm converged.	0,45	35,64	0,2112		0,25		Algorithm converged.	0,03	2,20
Age II	< 65	1564	87,7	24	1,5	1601	87,9	14	0,9	1,77		Algorithm converged.	0,91	3,43	0,007		Algorithm converged.	-0,001	0,014	1,75		Algorithm converged.	0,91	3,38	0,0926	0,9572	0,57		Algorithm converged.	0,30	1,10
	>= 65	219	12,3	9	4,1	221	12,1	5	2,3	1,85		Algorithm converged.	0,61	5,62	0,018		Algorithm converged.	-0,014	0,051	1,82		Algorithm converged.	0,62	5,33	0,2774		0,55		Algorithm converged.	0,19	1,62

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO												PERTUZUMAB vs PLACEBO		PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI1_S1.xls
05MAY2022 12:27

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Congestive heart failure / left ventricular dysfunction (SAEs), Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	18	1,0	1822	100,0	10	0,5	1,85		Algorithm converged.	0,85	4,01	0,005		Algorithm converged.	-0,001	0,010	1,84		Algorithm converged.	0,85	3,97	0,1210		0,54		Algorithm converged.	0,25	1,17
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	0	0,0	42	2,3	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE	-	NE			NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	1	0,4	4,24		Algorithm converged.	0,47	38,15	0,012		Algorithm converged.	-0,005	0,028	4,19		Algorithm converged.	0,47	37,20	0,1990		0,24		Algorithm converged.	0,03	2,12
	1-3 positive nodes	891	50,0	6	0,7	905	49,7	6	0,7	1,02		Algorithm converged.	0,33	3,16	0,000		Algorithm converged.	-0,007	0,008	1,02		Algorithm converged.	0,33	3,14	0,9784		0,98		Algorithm converged.	0,32	3,04
	>= 4 positive nodes	582	32,6	8	1,4	604	33,2	3	0,5	2,79		Algorithm converged.	0,74	10,58	0,009		Algorithm converged.	-0,002	0,020	2,77		Algorithm converged.	0,74	10,38	0,1313		0,36		Algorithm converged.	0,10	1,36
Geographical region II	USA/Canada	262	14,7	5	1,9	252	13,8	3	1,2	1,61		Algorithm converged.	0,38	6,83	0,007		Algorithm converged.	-0,014	0,028	1,60		Algorithm converged.	0,39	6,64	0,5151	-	0,62		Algorithm converged.	0,15	2,58
	Western Europe	814	45,7	7	0,9	824	45,2	5	0,6	1,42		Algorithm converged.	0,45	4,50	0,003		Algorithm converged.	-0,006	0,011	1,42		Algorithm converged.	0,45	4,45	0,5501		0,71		Algorithm converged.	0,22	2,21
	Asia Pacific	482	27,0	4	0,8	517	28,4	2	0,4	2,15		Algorithm converged.	0,39	11,82	0,004		Algorithm converged.	-0,005	0,014	2,15		Algorithm converged.	0,39	11,66	0,3769		0,47		Algorithm converged.	0,09	2,53
	Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE		NE			NE	NE
	Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age II	< 65	1564	87,7	13	0,8	1601	87,9	8	0,5	1,67		Algorithm converged.	0,69	4,04	0,003		Algorithm converged.	-0,002	0,009	1,66		Algorithm converged.	0,69	4,00	0,2559	-	0,60		Algorithm converged.	0,25	1,45

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	5	2,3	221	12,1	2	0,9	2,56		Algorithm converged.	0,49	13,33	0,014		Algorithm converged.	-0,010	0,037	2,52		Algorithm converged.	0,49	12,87	0,2656		0,40		Algorithm converged.	0,08	2,02

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI1G35_S1.xls
05MAY2022 12:34

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Grade >= 3 Diarrhea
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	169	9,5	1822	100,0	71	3,9	2,58		Algorithm converged.	1,94	3,43	0,056		Algorithm converged.	0,040	0,072	2,43		Algorithm converged.	1,86	3,18	<.0001		0,41		Algorithm converged.	0,31	0,54
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	5	11,9	0,63		Algorithm converged.	0,16	2,51	-0,041		Algorithm converged.	-0,163	0,082	0,66		Algorithm converged.	0,19	2,30	0,5128	-	1,52		Algorithm converged.	0,43	5,30
	0 positive nodes, tumor > 1 cm	259	14,5	25	9,7	271	14,9	15	5,5	1,82		Algorithm converged.	0,94	3,54	0,041		Algorithm converged.	-0,004	0,086	1,74		Algorithm converged.	0,94	3,23	0,0773		0,57		Algorithm converged.	0,31	1,06
	1-3 positive nodes	891	50,0	90	10,1	905	49,7	35	3,9	2,79		Algorithm converged.	1,87	4,18	0,062		Algorithm converged.	0,039	0,086	2,61		Algorithm converged.	1,79	3,82	<.0001		0,38		Algorithm converged.	0,26	0,56
	>= 4 positive nodes	582	32,6	50	8,6	604	33,2	16	2,6	3,45		Algorithm converged.	1,94	6,14	0,059		Algorithm converged.	0,033	0,086	3,24		Algorithm converged.	1,87	5,63	<.0001		0,31		Algorithm converged.	0,18	0,54
Geographical region II	USA/Canada	262	14,7	42	16,0	252	13,8	9	3,6	5,15		Algorithm converged.	2,45	10,83	0,125		Algorithm converged.	0,075	0,175	4,49		Algorithm converged.	2,23	9,03	<.0001	-	0,22		Algorithm converged.	0,11	0,45
	Western Europe	814	45,7	83	10,2	824	45,2	47	5,7	1,88		Algorithm converged.	1,29	2,72	0,045		Algorithm converged.	0,019	0,071	1,79		Algorithm converged.	1,27	2,52	0,0009		0,56		Algorithm converged.	0,40	0,79
	Asia Pacific	482	27,0	35	7,3	517	28,4	13	2,5	3,04		Algorithm converged.	1,59	5,81	0,047		Algorithm converged.	0,021	0,074	2,89		Algorithm converged.	1,55	5,39	0,0009		0,35		Algorithm converged.	0,19	0,65

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference						Relative Risk					Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Latin America	42	2,4	0	0,0	45	2,5	1	2,2	0,00		Algorithm converged.	0,00	NE	-0,045	*	WARNING: The relative Hessian convergence criterion of 8.3979945702 is greater than the limit of 0.0001. The convergence is questionable.	-0,359	0,269		0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE
	Other	183	10,3	9	4,9	184	10,1	1	0,5	9,47		Algorithm converged.	1,19	75,49	0,044		Algorithm converged.	0,011	0,077		9,05		Algorithm converged.	1,16	70,70	0,0357		0,11		Algorithm converged.	0,01	0,86
Age II	< 65	1564	87,7	131	8,4	1601	87,9	53	3,3	2,67		Algorithm converged.	1,93	3,70	0,051		Algorithm converged.	0,034	0,067		2,53		Algorithm converged.	1,85	3,45	<.0001	0,5853	0,40		Algorithm converged.	0,29	0,54
	>= 65	219	12,3	38	17,4	221	12,1	18	8,1	2,37		Algorithm converged.	1,31	4,29	0,092		Algorithm converged.	0,030	0,154		2,13		Algorithm converged.	1,26	3,61	0,0051		0,47		Algorithm converged.	0,28	0,80

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI2_S1.xls
05MAY2022 12:37

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Serious AESI: Grade >= 3 Diarrhea
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO										PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk Interaction Test p-value (likelihood ratio)		Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)			Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	34	1,9	1822	100,0	12	0,7	2,93		Algorithm converged.	1,51	5,68	0,012		Algorithm converged.	0,005	0,020	2,90		Algorithm converged.	1,50	5,57	0,0015		0,35		Algorithm converged.	0,18	0,66
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	3	1,2	271	14,9	2	0,7	1,58		Algorithm converged.	0,26	9,51	0,004		Algorithm converged.	-0,012	0,021	1,57		Algorithm converged.	0,26	9,32	0,6199		0,64		Algorithm converged.	0,11	3,78
	1-3 positive nodes	891	50,0	17	1,9	905	49,7	6	0,7	2,91		Algorithm converged.	1,14	7,43	0,012		Algorithm converged.	0,002	0,023	2,88		Algorithm converged.	1,14	7,27	0,0253		0,35		Algorithm converged.	0,14	0,88
	>= 4 positive nodes	582	32,6	13	2,2	604	33,2	4	0,7	3,43		Algorithm converged.	1,11	10,57	0,016		Algorithm converged.	0,002	0,029	3,37		Algorithm converged.	1,11	10,28	0,0326		0,30		Algorithm converged.	0,10	0,90
Geographical region II	USA/Canada	262	14,7	8	3,1	252	13,8	1	0,4	7,91		Algorithm converged.	0,98	63,67	0,027		Algorithm converged.	0,004	0,049	7,69		Algorithm converged.	0,97	61,08	0,0535	-	0,13		Algorithm converged.	0,02	1,03
	Western Europe	814	45,7	17	2,1	824	45,2	8	1,0	2,18		Algorithm converged.	0,93	5,07	0,011		Algorithm converged.	-0,001	0,023	2,15		Algorithm converged.	0,93	4,96	0,0721		0,46		Algorithm converged.	0,20	1,07
	Asia Pacific	482	27,0	8	1,7	517	28,4	2	0,4	4,35		Algorithm converged.	0,92	20,57	0,013		Algorithm converged.	0,000	0,025	4,29		Algorithm converged.	0,92	20,10	0,0646		0,23		Algorithm converged.	0,05	1,09
	Latin America	42	2,4	0	0,0	45	2,5	0	0,0	NE			NE	NE	NE			NE	NE	NE			NE	NE	NE			NE			NE	NE
	Other	183	10,3	1	0,5	184	10,1	1	0,5	1,01		Algorithm converged.	0,06	16,20	0,000		Algorithm converged.	-0,015	0,015	1,01		Algorithm converged.	0,06	15,95	0,9969		0,99		Algorithm converged.	0,06	15,78
Age II	< 65	1564	87,7	22	1,4	1601	87,9	9	0,6	2,52		Algorithm converged.	1,16	5,50	0,008		Algorithm converged.	0,002	0,015	2,50		Algorithm converged.	1,16	5,42	0,0199	0,5150	0,40		Algorithm converged.	0,18	0,87

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO						PLACEBO vs PERTUZUMAB					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL						
	>= 65	219	12,3	12	5,5	221	12,1	3	1,4	4,21		Algorithm converged.	1,17	15,14	0,041		Algorithm converged.	0,007	0,075	4,04		Algorithm converged.	1,16	14,11	0,0288		0,25		Algorithm converged.	0,07	0,87						

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI2SAE_S1.xls
05MAY2022 12:40

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Hypersensitivity reactions / anaphylaxis
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	83	4,7	1822	100,0	68	3,7	1,26		Algorithm converged.	0,91	1,75	0,009		Algorithm converged.	-0,004	0,022	1,25		Algorithm converged.	0,91	1,71	0,1676		0,80		Algorithm converged.	0,59	1,10
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	3	5,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	14	5,4	271	14,9	15	5,5	0,98		Algorithm converged.	0,46	2,06	-0,001		Algorithm converged.	-0,040	0,037	0,98		Algorithm converged.	0,48	1,98	0,9477		1,02		Algorithm converged.	0,50	2,08
	1-3 positive nodes	891	50,0	36	4,0	905	49,7	35	3,9	1,05		Algorithm converged.	0,65	1,68	0,002		Algorithm converged.	-0,016	0,020	1,04		Algorithm converged.	0,66	1,65	0,8508		0,96		Algorithm converged.	0,61	1,51
	>= 4 positive nodes	582	32,6	30	5,2	604	33,2	18	3,0	1,77		Algorithm converged.	0,98	3,21	0,022		Algorithm converged.	-0,001	0,044	1,73		Algorithm converged.	0,98	3,07	0,0610		0,58		Algorithm converged.	0,33	1,03
Geographical region II	USA/Canada	262	14,7	15	5,7	252	13,8	10	4,0	1,47		Algorithm converged.	0,65	3,34	0,018		Algorithm converged.	-0,019	0,055	1,44		Algorithm converged.	0,66	3,15	0,3578	-	0,69		Algorithm converged.	0,32	1,51
	Western Europe	814	45,7	34	4,2	824	45,2	31	3,8	1,12		Algorithm converged.	0,68	1,83	0,004		Algorithm converged.	-0,015	0,023	1,11		Algorithm converged.	0,69	1,79	0,6674		0,90		Algorithm converged.	0,56	1,45
	Asia Pacific	482	27,0	23	4,8	517	28,4	16	3,1	1,57		Algorithm converged.	0,82	3,01	0,017		Algorithm converged.	-0,007	0,041	1,54		Algorithm converged.	0,82	2,88	0,1751		0,65		Algorithm converged.	0,35	1,21
	Latin America	42	2,4	3	7,1	45	2,5	6	13,3	0,50		Algorithm converged.	0,12	2,14	-0,062		Algorithm converged.	-0,188	0,064	0,54		Algorithm converged.	0,14	2,01	0,3543		1,87		Algorithm converged.	0,50	6,99
	Other	183	10,3	8	4,4	184	10,1	5	2,7	1,64		Algorithm converged.	0,53	5,10	0,017		Algorithm converged.	-0,021	0,054	1,61		Algorithm converged.	0,54	4,83	0,3962		0,62		Algorithm converged.	0,21	1,86
Age II	< 65	1564	87,7	73	4,7	1601	87,9	63	3,9	1,20		Algorithm converged.	0,85	1,69	0,007		Algorithm converged.	-0,007	0,021	1,19		Algorithm converged.	0,85	1,65	0,3103	0,3364	0,84		Algorithm converged.	0,61	1,17

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	10	4,6	221	12,1	5	2,3	2,07		Algorithm converged.	0,69	6,15	0,023		Algorithm converged.	-0,011	0,057	2,02		Algorithm converged.	0,70	5,81	0,1929		0,50		Algorithm converged.	0,17	1,43

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI3_S1.xls
05MAY2022 12:42

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Hypersensitivity reactions / anaphylaxis, Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	13	0,7	1822	100,0	16	0,9	0,83		Algorithm converged.	0,40	1,73	-0,001		Algorithm converged.	-0,007	0,004	0,83		Algorithm converged.	0,40	1,72	0,6170		1,20		Algorithm converged.	0,58	2,50
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	1	0,4	271	14,9	2	0,7	0,52		Algorithm converged.	0,05	5,78	-0,004		Algorithm converged.	-0,016	0,009	0,52		Algorithm converged.	0,05	5,73	0,5959		1,91		Algorithm converged.	0,17	20,95
	1-3 positive nodes	891	50,0	5	0,6	905	49,7	11	1,2	0,46		Algorithm converged.	0,16	1,33	-0,007		Algorithm converged.	-0,015	0,002	0,46		Algorithm converged.	0,16	1,32	0,1503		2,17		Algorithm converged.	0,76	6,21
	>= 4 positive nodes	582	32,6	5	0,9	604	33,2	3	0,5	1,74		Algorithm converged.	0,41	7,30	0,004		Algorithm converged.	-0,006	0,013	1,73		Algorithm converged.	0,42	7,20	0,4517		0,58		Algorithm converged.	0,14	2,41
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	4	1,6	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE
	Western Europe	814	45,7	9	1,1	824	45,2	9	1,1	1,01		Algorithm converged.	0,40	2,56	0,000		Algorithm converged.	-0,010	0,010	1,01		Algorithm converged.	0,40	2,54	0,9792		0,99		Algorithm converged.	0,39	2,48
	Asia Pacific	482	27,0	2	0,4	517	28,4	1	0,2	2,15		Algorithm converged.	0,19	23,79	0,002		Algorithm converged.	-0,005	0,009	2,15		Algorithm converged.	0,20	23,58	0,5326		0,47		Algorithm converged.	0,04	5,12

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Latin America	42	2,4	1	2,4	45	2,5	2	4,4	0,52		Algorithm converged.	0,05	6,01	-0,021		Algorithm converged.	-0,096	0,055	0,54		Algorithm converged.	0,05	5,69	0,6047		1,87		Algorithm converged.	0,18	19,84
	Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age II	< 65	1564	87,7	13	0,8	1601	87,9	14	0,9	0,95		Algorithm converged.	0,45	2,03	0,000		Algorithm converged.	-0,007	0,006	0,95		Algorithm converged.	0,45	2,02	0,8948	-	1,05		Algorithm converged.	0,50	2,23
	>= 65	219	12,3	0	0,0	221	12,1	2	0,9	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999		>999		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI3G35_S1.xls
05MAY2022 12:47

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Serious AESI: Hypersensitivity reactions / anaphylaxis
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	11	0,6	1822	100,0	8	0,4	1,41		Algorithm converged.	0,56	3,51	0,002		Algorithm converged.	-0,003	0,007	1,41		Algorithm converged.	0,57	3,48	0,4631		0,71		Algorithm converged.	0,29	1,77
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
	1-3 positive nodes	891	50,0	5	0,6	905	49,7	4	0,4	1,27		Algorithm converged.	0,34	4,75	0,001		Algorithm converged.	-0,005	0,008	1,27		Algorithm converged.	0,34	4,71	0,7213		0,79		Algorithm converged.	0,21	2,92
	>= 4 positive nodes	582	32,6	3	0,5	604	33,2	3	0,5	1,04		Algorithm converged.	0,21	5,16	0,000		Algorithm converged.	-0,008	0,008	1,04		Algorithm converged.	0,21	5,12	0,9637		0,96		Algorithm converged.	0,20	4,75
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	1	0,4	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO													PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Western Europe	814	45,7	7	0,9	824	45,2	6	0,7	1,18		Algorithm converged.	0,40	3,53	0,001		Algorithm converged.	-0,007	0,010	1,18		Algorithm converged.	0,40	3,50	0,7640		0,85		Algorithm converged.	0,29	2,51
	Asia Pacific	482	27,0	2	0,4	517	28,4	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
	Other	183	10,3	1	0,5	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age II	< 65	1564	87,7	10	0,6	1601	87,9	7	0,4	1,47		Algorithm converged.	0,56	3,86	0,002		Algorithm converged.	-0,003	0,007	1,46		Algorithm converged.	0,56	3,83	0,4394	-	0,68		Algorithm converged.	0,26	1,79
	>= 65	219	12,3	1	0,5	221	12,1	1	0,5	1,01		Algorithm converged.	0,06	16,24	0,000		Algorithm converged.	-0,013	0,013	1,01		Algorithm converged.	0,06	16,03	0,9949		0,99		Algorithm converged.	0,06	15,74

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI3SAE_S1.xls
05MAY2022 12:49

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Infusion-related reactions
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	954	53,5	1822	100,0	898	49,3	1,18		Algorithm converged.	1,04	1,35	0,042		Algorithm converged.	0,010	0,075	1,09		Algorithm converged.	1,02	1,16	0,0113		0,92		Algorithm converged.	0,86	0,98
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	36	70,6	42	2,3	21	50,0	2,40		Algorithm converged.	1,02	5,64	0,206		Algorithm converged.	0,010	0,402	1,41		Algorithm converged.	0,99	2,00	0,0538	0,2395	0,71		Algorithm converged.	0,50	1,01
	0 positive nodes, tumor > 1 cm	259	14,5	148	57,1	271	14,9	131	48,3	1,42		Algorithm converged.	1,01	2,01	0,088		Algorithm converged.	0,003	0,173	1,18		Algorithm converged.	1,01	1,39	0,0431		0,85		Algorithm converged.	0,72	0,99
	1-3 positive nodes	891	50,0	482	54,1	905	49,7	469	51,8	1,10		Algorithm converged.	0,91	1,32	0,023		Algorithm converged.	-0,023	0,069	1,04		Algorithm converged.	0,96	1,14	0,3346		0,96		Algorithm converged.	0,88	1,05
	>= 4 positive nodes	582	32,6	288	49,5	604	33,2	277	45,9	1,16		Algorithm converged.	0,92	1,45	0,036		Algorithm converged.	-0,021	0,093	1,08		Algorithm converged.	0,96	1,22	0,2117		0,93		Algorithm converged.	0,82	1,04
Geographical region II	USA/Canada	262	14,7	192	73,3	252	13,8	170	67,5	1,32		Algorithm converged.	0,90	1,93	0,058		Algorithm converged.	-0,021	0,137	1,09		Algorithm converged.	0,97	1,22	0,1499	0,4203	0,92		Algorithm converged.	0,82	1,03
	Western Europe	814	45,7	465	57,1	824	45,2	444	53,9	1,14		Algorithm converged.	0,94	1,39	0,032		Algorithm converged.	-0,016	0,081	1,06		Algorithm converged.	0,97	1,16	0,1870		0,94		Algorithm converged.	0,86	1,03
	Asia Pacific	482	27,0	231	47,9	517	28,4	229	44,3	1,16		Algorithm converged.	0,90	1,48	0,036		Algorithm converged.	-0,026	0,098	1,08		Algorithm converged.	0,95	1,24	0,2498		0,92		Algorithm converged.	0,81	1,06
	Latin America	42	2,4	12	28,6	45	2,5	17	37,8	0,66		Algorithm converged.	0,27	1,62	-0,092		Algorithm converged.	-0,289	0,105	0,76		Algorithm converged.	0,41	1,39	0,3676		1,32		Algorithm converged.	0,72	2,43
	Other	183	10,3	54	29,5	184	10,1	38	20,7	1,61		Algorithm converged.	1,00	2,59	0,089		Algorithm converged.	0,000	0,177	1,43		Algorithm converged.	1,00	2,05	0,0527		0,70		Algorithm converged.	0,49	1,00
Age II	< 65	1564	87,7	853	54,5	1601	87,9	797	49,8	1,21		Algorithm converged.	1,05	1,39	0,048		Algorithm converged.	0,013	0,082	1,10		Algorithm converged.	1,02	1,17	0,0074	0,4509	0,91		Algorithm converged.	0,85	0,98
	>= 65	219	12,3	101	46,1	221	12,1	101	45,7	1,02		Algorithm converged.	0,70	1,48	0,004		Algorithm converged.	-0,089	0,097	1,01		Algorithm converged.	0,82	1,24	0,9300		0,99		Algorithm converged.	0,81	1,21

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI4_S1.xls
05MAY2022 12:51

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Infusion-related reactions, Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	41	2,3	1822	100,0	48	2,6	0,87		Algorithm converged.	0,57	1,33	-0,003		Algorithm converged.	-0,013	0,007	0,87		Algorithm converged.	0,58	1,32	0,5173		1,15		Algorithm converged.	0,76	1,73
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	5	9,8	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	0,118	*	WARNING: The relative Hessian convergence criterion of 2.5654043887 is greater than the limit of 0.0001. The convergence is questionable.	-0,200	0,435	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	6	2,3	271	14,9	6	2,2	1,05		Algorithm converged.	0,33	3,29	0,001		Algorithm converged.	-0,024	0,026	1,05		Algorithm converged.	0,34	3,20	0,9368		0,96		Algorithm converged.	0,31	2,93
	1-3 positive nodes	891	50,0	17	1,9	905	49,7	32	3,5	0,53		Algorithm converged.	0,29	0,96	-0,016		Algorithm converged.	-0,031	-0,001	0,54		Algorithm converged.	0,30	0,96	0,0374		1,85		Algorithm converged.	1,04	3,31
	>= 4 positive nodes	582	32,6	13	2,2	604	33,2	10	1,7	1,36		Algorithm converged.	0,59	3,12	0,006		Algorithm converged.	-0,010	0,022	1,35		Algorithm converged.	0,60	3,05	0,4722		0,74		Algorithm converged.	0,33	1,68
Geographical region II	USA/Canada	262	14,7	7	2,7	252	13,8	8	3,2	0,84		Algorithm converged.	0,30	2,34	-0,005		Algorithm converged.	-0,034	0,024	0,84		Algorithm converged.	0,31	2,29	0,7353	-	1,19		Algorithm converged.	0,44	3,23
	Western Europe	814	45,7	25	3,1	824	45,2	28	3,4	0,90		Algorithm converged.	0,52	1,56	-0,003		Algorithm converged.	-0,020	0,014	0,90		Algorithm converged.	0,53	1,54	0,7087		1,11		Algorithm converged.	0,65	1,88

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Asia Pacific	482	27,0	4	0,8	517	28,4	7	1,4	0,61		Algorithm converged.	0,18	2,10	-0,005		Algorithm converged.	-0,018	0,008	0,61		Algorithm converged.	0,18	2,08	0,4324		1,63		Algorithm converged.	0,48	5,54
	Latin America	42	2,4	1	2,4	45	2,5	3	6,7	0,34		Algorithm converged.	0,03	3,42	-0,043		Algorithm converged.	-0,129	0,043	0,36		Algorithm converged.	0,04	3,30	0,3642		2,80		Algorithm converged.	0,30	25,88
	Other	183	10,3	4	2,2	184	10,1	2	1,1	2,03		Algorithm converged.	0,37	11,24	0,011		Algorithm converged.	-0,015	0,037	2,01		Algorithm converged.	0,37	10,84	0,4164		0,50		Algorithm converged.	0,09	2,68
Age II	< 65	1564	87,7	40	2,6	1601	87,9	40	2,5	1,02		Algorithm converged.	0,66	1,60	0,001		Algorithm converged.	-0,010	0,012	1,02		Algorithm converged.	0,66	1,58	0,9157	-	0,98		Algorithm converged.	0,63	1,51
	>= 65	219	12,3	1	0,5	221	12,1	8	3,6	0,12		Algorithm converged.	0,02	0,98	-0,032		Algorithm converged.	-0,058	-0,005	0,13		Algorithm converged.	0,02	1,00	0,0500		7,93		Algorithm converged.	1,00	62,85

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI4G35_S1.xls
05MAY2022 12:52

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Serious AESI: Infusion-related reactions
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	14	0,8	1822	100,0	16	0,9	0,89		Algorithm converged.	0,43	1,84	-0,001		Algorithm converged.	-0,007	0,005	0,89		Algorithm converged.	0,44	1,83	0,7588		1,12		Algorithm converged.	0,55	2,28
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	1	2,0	42	2,3	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE		Algorithm converged.	NE	NE	NE	-	NE		Algorithm converged.	NE	NE
	0 positive nodes, tumor > 1 cm	259	14,5	2	0,8	271	14,9	1	0,4	2,10		Algorithm converged.	0,19	23,31	0,004		Algorithm converged.	-0,009	0,017	2,09		Algorithm converged.	0,19	22,94	0,5455		0,48		Algorithm converged.	0,04	5,24
	1-3 positive nodes	891	50,0	7	0,8	905	49,7	9	1,0	0,79		Algorithm converged.	0,29	2,13	-0,002		Algorithm converged.	-0,011	0,007	0,79		Algorithm converged.	0,30	2,11	0,6385		1,27		Algorithm converged.	0,47	3,38
	>= 4 positive nodes	582	32,6	4	0,7	604	33,2	6	1,0	0,69		Algorithm converged.	0,19	2,46	-0,003		Algorithm converged.	-0,013	0,007	0,69		Algorithm converged.	0,20	2,44	0,5667		1,45		Algorithm converged.	0,41	5,10
Geographical region II	USA/Canada	262	14,7	0	0,0	252	13,8	2	0,8	0,00		Algorithm converged.	0,00	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	0,00		Algorithm converged.	0,00	NE	0,9999	-	>999		Algorithm converged.	0,00	NE

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	Western Europe	814	45,7	6	0,7	824	45,2	8	1,0	0,76		Algorithm converged.	0,26	2,19	-0,002		Algorithm converged.	-0,011	0,007	0,76		Algorithm converged.	0,26	2,18	0,6085		1,32		Algorithm converged.	0,46	3,78
	Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013	1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
	Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
	Other	183	10,3	3	1,6	184	10,1	2	1,1	1,52		Algorithm converged.	0,25	9,18	0,006		Algorithm converged.	-0,018	0,029	1,51		Algorithm converged.	0,25	8,92	0,6505		0,66		Algorithm converged.	0,11	3,92
Age II	< 65	1564	87,7	11	0,7	1601	87,9	15	0,9	0,75		Algorithm converged.	0,34	1,64	-0,002		Algorithm converged.	-0,009	0,004	0,75		Algorithm converged.	0,35	1,63	0,4682	-	1,33		Algorithm converged.	0,61	2,89
	>= 65	219	12,3	3	1,4	221	12,1	1	0,5	3,06		Algorithm converged.	0,32	29,60	0,009		Algorithm converged.	-0,009	0,027	3,03		Algorithm converged.	0,32	28,88	0,3358		0,33		Algorithm converged.	0,03	3,15

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI4SAE_S1.xls
05MAY2022 12:54

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Administration-related reactions
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	1109	62,2	1822	100,0	996	54,7	1,36		Algorithm converged.	1,19	1,56	0,075		Algorithm converged.	0,043	0,107	1,14		Algorithm converged.	1,08	1,20	<.0001		0,88		Algorithm converged.	0,83	0,93
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	33	64,7	42	2,3	25	59,5	1,25		Algorithm converged.	0,54	2,89	0,052		Algorithm converged.	-0,146	0,250	1,09		Algorithm converged.	0,79	1,50	0,6107	0,8402	0,92		Algorithm converged.	0,67	1,27
	0 positive nodes, tumor > 1 cm	259	14,5	179	69,1	271	14,9	165	60,9	1,44		Algorithm converged.	1,00	2,06	0,082		Algorithm converged.	0,001	0,163	1,14		Algorithm converged.	1,00	1,29	0,0477		0,88		Algorithm converged.	0,78	1,00
	1-3 positive nodes	891	50,0	551	61,8	905	49,7	502	55,5	1,30		Algorithm converged.	1,08	1,57	0,064		Algorithm converged.	0,018	0,109	1,11		Algorithm converged.	1,03	1,21	0,0062		0,90		Algorithm converged.	0,83	0,97
	>= 4 positive nodes	582	32,6	346	59,5	604	33,2	304	50,3	1,45		Algorithm converged.	1,15	1,82	0,091		Algorithm converged.	0,035	0,148	1,18		Algorithm converged.	1,06	1,31	0,0017		0,85		Algorithm converged.	0,76	0,94
Geographical region II	USA/Canada	262	14,7	198	75,6	252	13,8	173	68,7	1,41		Algorithm converged.	0,96	2,08	0,069		Algorithm converged.	-0,008	0,147	1,10		Algorithm converged.	0,99	1,23	0,0818	0,5796	0,91		Algorithm converged.	0,82	1,01
	Western Europe	814	45,7	519	63,8	824	45,2	471	57,2	1,32		Algorithm converged.	1,08	1,61	0,066		Algorithm converged.	0,019	0,113	1,12		Algorithm converged.	1,03	1,21	0,0064		0,90		Algorithm converged.	0,83	0,97
	Asia Pacific	482	27,0	302	62,7	517	28,4	273	52,8	1,50		Algorithm converged.	1,16	1,93	0,099		Algorithm converged.	0,038	0,159	1,19		Algorithm converged.	1,07	1,32	0,0017		0,84		Algorithm converged.	0,76	0,94
	Latin America	42	2,4	14	33,3	45	2,5	18	40,0	0,75		Algorithm converged.	0,31	1,80	-0,067		Algorithm converged.	-0,269	0,135	0,83		Algorithm converged.	0,48	1,46	0,5217		1,20		Algorithm converged.	0,69	2,10
	Other	183	10,3	76	41,5	184	10,1	61	33,2	1,43		Algorithm converged.	0,94	2,19	0,084		Algorithm converged.	-0,015	0,182	1,25		Algorithm converged.	0,96	1,64	0,0990		0,80		Algorithm converged.	0,61	1,04
Age II	< 65	1564	87,7	967	61,8	1601	87,9	883	55,2	1,32		Algorithm converged.	1,14	1,52	0,067		Algorithm converged.	0,033	0,101	1,12		Algorithm converged.	1,06	1,19	0,0001	0,1569	0,89		Algorithm converged.	0,84	0,95
	>= 65	219	12,3	142	64,8	221	12,1	113	51,1	1,76		Algorithm converged.	1,20	2,58	0,137		Algorithm converged.	0,046	0,228	1,27		Algorithm converged.	1,08	1,49	0,0040		0,79		Algorithm converged.	0,67	0,93

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO								PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI5_S1.xls
05MAY2022 13:03

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: AESI: Administration-related reactions, Grade >= 3
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	40	2,2	1822	100,0	45	2,5	0,91		Algorithm converged.	0,59	1,39	-0,002		Algorithm converged.	-0,012	0,008	0,91		Algorithm converged.	0,60	1,38	0,6543		1,10		Algorithm converged.	0,72	1,68
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	4	7,8	42	2,3	2	4,8	1,70		Algorithm converged.	0,30	9,78	0,031		Algorithm converged.	-0,067	0,129	1,65		Algorithm converged.	0,32	8,55	0,5528	-	0,61		Algorithm converged.	0,12	3,15
	0 positive nodes, tumor > 1 cm	259	14,5	5	1,9	271	14,9	5	1,8	1,05		Algorithm converged.	0,30	3,66	0,001		Algorithm converged.	-0,022	0,024	1,05		Algorithm converged.	0,31	3,57	0,9424		0,96		Algorithm converged.	0,28	3,26
	1-3 positive nodes	891	50,0	19	2,1	905	49,7	27	3,0	0,71		Algorithm converged.	0,39	1,28	-0,009		Algorithm converged.	-0,023	0,006	0,71		Algorithm converged.	0,40	1,28	0,2561		1,40		Algorithm converged.	0,78	2,50
	>= 4 positive nodes	582	32,6	12	2,1	604	33,2	11	1,8	1,13		Algorithm converged.	0,50	2,59	0,002		Algorithm converged.	-0,013	0,018	1,13		Algorithm converged.	0,50	2,55	0,7640		0,88		Algorithm converged.	0,39	1,99
Geographical region II	USA/Canada	262	14,7	5	1,9	252	13,8	8	3,2	0,59		Algorithm converged.	0,19	1,84	-0,013		Algorithm converged.	-0,040	0,015	0,60		Algorithm converged.	0,20	1,81	0,3662	-	1,66		Algorithm converged.	0,55	5,02
	Western Europe	814	45,7	28	3,4	824	45,2	31	3,8	0,91		Algorithm converged.	0,54	1,53	-0,003		Algorithm converged.	-0,021	0,015	0,91		Algorithm converged.	0,55	1,51	0,7264		1,09		Algorithm converged.	0,66	1,81
	Asia Pacific	482	27,0	3	0,6	517	28,4	4	0,8	0,80		Algorithm converged.	0,18	3,61	-0,002		Algorithm converged.	-0,012	0,009	0,80		Algorithm converged.	0,18	3,58	0,7750		1,24		Algorithm converged.	0,28	5,53
	Latin America	42	2,4	2	4,8	45	2,5	2	4,4	1,07		Algorithm converged.	0,14	8,00	0,003		Algorithm converged.	-0,085	0,091	1,07		Algorithm converged.	0,16	7,27	0,9437		0,93		Algorithm converged.	0,14	6,33
	Other	183	10,3	2	1,1	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age II	< 65	1564	87,7	37	2,4	1601	87,9	37	2,3	1,02		Algorithm converged.	0,65	1,62	0,001		Algorithm converged.	-0,010	0,011	1,02		Algorithm converged.	0,65	1,61	0,9189	0,1399	0,98		Algorithm converged.	0,62	1,53

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO														PERTUZUMAB vs PLACEBO					PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	3	1,4	221	12,1	8	3,6	0,37		Algorithm converged.	0,10	1,41	-0,023		Algorithm converged.	-0,052	0,007	0,38		Algorithm converged.	0,10	1,41	0,1471		2,64		Algorithm converged.	0,71	9,83

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI5G35_S1.xls
05MAY2022 13:07

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Serious AESI: Administration-related reactions
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO									PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	1783	100,0	27	1,5	1822	100,0	24	1,3	1,15		Algorithm converged.	0,66	2,00	0,002		Algorithm converged.	-0,006	0,010	1,15		Algorithm converged.	0,67	1,98	0,6167		0,87		Algorithm converged.	0,50	1,50
Nodal status and tumor size	0 positive nodes, tumor <= 1 cm	51	2,9	2	3,9	42	2,3	1	2,4	1,67		Algorithm converged.	0,15	19,12	0,015		Algorithm converged.	-0,055	0,086	1,65		Algorithm converged.	0,15	17,54	0,6793	-	0,61		Algorithm converged.	0,06	6,47
	0 positive nodes, tumor > 1 cm	259	14,5	4	1,5	271	14,9	3	1,1	1,40		Algorithm converged.	0,31	6,32	0,004		Algorithm converged.	-0,015	0,024	1,40		Algorithm converged.	0,32	6,17	0,6608		0,72		Algorithm converged.	0,16	3,17
	1-3 positive nodes	891	50,0	13	1,5	905	49,7	12	1,3	1,10		Algorithm converged.	0,50	2,43	0,001		Algorithm converged.	-0,010	0,012	1,10		Algorithm converged.	0,50	2,40	0,8099		0,91		Algorithm converged.	0,42	1,98
	>= 4 positive nodes	582	32,6	8	1,4	604	33,2	8	1,3	1,04		Algorithm converged.	0,39	2,79	0,001		Algorithm converged.	-0,013	0,014	1,04		Algorithm converged.	0,39	2,75	0,9404		0,96		Algorithm converged.	0,36	2,55
Geographical region II	USA/Canada	262	14,7	5	1,9	252	13,8	6	2,4	0,80		Algorithm converged.	0,24	2,65	-0,005		Algorithm converged.	-0,030	0,020	0,80		Algorithm converged.	0,25	2,59	0,7119	-	1,25		Algorithm converged.	0,39	4,04
	Western Europe	814	45,7	13	1,6	824	45,2	14	1,7	0,94		Algorithm converged.	0,44	2,01	-0,001		Algorithm converged.	-0,013	0,011	0,94		Algorithm converged.	0,44	1,99	0,8713		1,06		Algorithm converged.	0,50	2,25
	Asia Pacific	482	27,0	4	0,8	517	28,4	3	0,6	1,43		Algorithm converged.	0,32	6,44	0,002		Algorithm converged.	-0,008	0,013	1,43		Algorithm converged.	0,32	6,36	0,6383		0,70		Algorithm converged.	0,16	3,11
	Latin America	42	2,4	1	2,4	45	2,5	1	2,2	1,07		Algorithm converged.	0,06	17,72	0,002		Algorithm converged.	-0,062	0,065	1,07		Algorithm converged.	0,07	16,59	0,9606		0,93		Algorithm converged.	0,06	14,45
	Other	183	10,3	4	2,2	184	10,1	0	0,0	NE		Algorithm converged.	NE	NE	NE	*	WARNING: Negative of Hessian not positive definite.	NE	NE	NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age II	< 65	1564	87,7	23	1,5	1601	87,9	20	1,2	1,18		Algorithm converged.	0,65	2,16	0,002		Algorithm converged.	-0,006	0,010	1,18		Algorithm converged.	0,65	2,13	0,5911	-	0,85		Algorithm converged.	0,47	1,54

		PERTUZUMAB (N=1783)				PLACEBO (N=1822)				PERTUZUMAB vs PLACEBO										PERTUZUMAB vs PLACEBO							PLACEBO vs PERTUZUMAB				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
	>= 65	219	12,3	4	1,8	221	12,1	4	1,8	1,01		Algorithm converged.	0,25	4,09	0,000		Algorithm converged.	-0,025	0,025	1,01		Algorithm converged.	0,26	3,98	0,9896		0,99		Algorithm converged.	0,25	3,91

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_raw.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_raw_26d_10JAN2022_CHNS_AESI5SAE_S1.xls
05MAY2022 13:09

Verträglichkeit (Datenschnitt: 10.01.2022)

Outcome

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Outcome of adverse events

		PERTUZUMAB (N=1783)																PLACEBO (N=1822)													
		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																															
	All	38053	100,0	35210	92,5	83	0,2	606	1,6	10	<0.1	38	<0.1	115	0,3	1991	5,2	34918	100,0	32257	92,4	64	0,2	689	2,0	11	<0.1	50	0,1	160	0,5	1687	4,8
AEs Grade 3																															
	All	2164	100,0	2029	93,8	17	0,8	35	1,6	0	0,0	3	0,1	5	0,2	75	3,5	1987	100,0	1847	93,0	16	0,8	46	2,3	0	0,0	2	0,1	5	0,3	71	3,6
AEs Grade 4																															
	All	598	100,0	585	97,8	4	0,7	6	1,0	0	0,0	0	0,0	1	0,2	2	0,3	602	100,0	590	98,0	5	0,8	6	1,0	0	0,0	0	0,0	0	0,0	1	0,2
Any SAEs																															
	All	799	100,0	743	93,0	25	3,1	5	0,6	10	1,3	1	0,1	0	0,0	15	1,9	690	100,0	642	93,0	16	2,3	7	1,0	11	1,6	3	0,4	3	0,4	8	1,2
	Grade 1	35	100,0	34	97,1	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	2,9	39	100,0	37	94,9	0	0,0	1	2,6	0	0,0	0	0,0	0	0,0	1	2,6
	Grade 2	162	100,0	150	92,6	8	4,9	0	0,0	0	0,0	0	0,0	0	0,0	4	2,5	131	100,0	121	92,4	4	3,1	2	1,5	0	0,0	2	1,5	0	0,0	2	1,5
	Grade 3	439	100,0	414	94,3	13	3,0	2	0,5	0	0,0	1	0,2	0	0,0	9	2,1	374	100,0	358	95,7	7	1,9	3	0,8	0	0,0	1	0,3	3	0,8	2	0,5
	Grade 4	152	100,0	145	95,4	4	2,6	3	2,0	0	0,0	0	0,0	0	0,0	0	0,0	132	100,0	125	94,7	5	3,8	1	0,8	0	0,0	0	0,0	0	0,0	1	0,8
	Grade 5	10	100,0	0	0,0	0	0,0	0	0,0	10	100,0	0	0,0	0	0,0	0	0,0	11	100,0	0	0,0	0	0,0	0	0,0	11	100,0	0	0,0	0	0,0	0	0,0
	Missing	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	100,0	3	100,0	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	66,7
AESI: Congestive heart failure / left ventricular dysfunction (SAEs)																															
	All	37	100,0	24	64,9	4	10,8	1	2,7	0	0,0	0	0,0	0	0,0	8	21,6	19	100,0	16	84,2	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	3	15,8
	Grade 1	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 2	19	100,0	13	68,4	4	21,1	0	0,0	0	0,0	0	0,0	0	0,0	2	10,5	9	100,0	7	77,8	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	22,2
	Grade 3	15	100,0	9	60,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	6	40,0	10	100,0	9	90,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	10,0
	Grade 4	3	100,0	2	66,7	0	0,0	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 5	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Missing	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
AESI: Grade >= 3 Diarrhea																															
	All	186	100,0	180	96,8	1	0,5	3	1,6	0	0,0	1	0,5	0	0,0	1	0,5	75	100,0	75	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 3	183	100,0	177	96,7	1	0,5	3	1,6	0	0,0	1	0,5	0	0,0	1	0,5	75	100,0	75	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 4	3	100,0	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 5	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Missing	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

		PERTUZUMAB (N=1783)																PLACEBO (N=1822)															
		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
AESI: Hypersensitivity reactions / anaphylaxis																																	
	All	101	100,0	101	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	93	100,0	92	98,9	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1,1
	Grade 1	37	100,0	37	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	31	100,0	31	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 2	49	100,0	49	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	43	100,0	43	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 3	13	100,0	13	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	16	100,0	16	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 4	2	100,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	100,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 5	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Missing	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	100,0
AESI: Infusion-related reactions																																	
	All	2175	100,0	1905	87,6	3	0,1	51	2,3	0	0,0	4	0,2	9	0,4	203	9,3	2050	100,0	1848	90,1	3	0,1	50	2,4	0	0,0	4	0,2	10	0,5	135	6,6
	Grade 1	1649	100,0	1475	89,4	2	0,1	37	2,2	0	0,0	4	0,2	5	0,3	126	7,6	1511	100,0	1401	92,7	1	<0.1	38	2,5	0	0,0	1	<0.1	9	0,6	61	4,0
	Grade 2	442	100,0	386	87,3	1	0,2	14	3,2	0	0,0	0	0,0	3	0,7	38	8,6	455	100,0	401	88,1	1	0,2	10	2,2	0	0,0	3	0,7	1	0,2	39	8,6
	Grade 3	48	100,0	43	89,6	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	5	10,4	52	100,0	44	84,6	1	1,9	2	3,8	0	0,0	0	0,0	0	0,0	5	9,6
	Grade 4	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	100,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 5	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Missing	36	100,0	1	2,8	0	0,0	0	0,0	0	0,0	0	0,0	1	2,8	34	94,4	30	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	30	100,0
AESI: Administration-related reactions																																	
	All	2360	100,0	2218	94,0	4	0,2	29	1,2	0	0,0	4	0,2	12	0,5	93	3,9	2126	100,0	2014	94,7	5	0,2	32	1,5	0	0,0	4	0,2	4	0,2	67	3,2
	Grade 1	1785	100,0	1698	95,1	3	0,2	19	1,1	0	0,0	3	0,2	6	0,3	56	3,1	1610	100,0	1539	95,6	2	0,1	20	1,2	0	0,0	2	0,1	4	0,2	43	2,7
	Grade 2	507	100,0	477	94,1	1	0,2	8	1,6	0	0,0	0	0,0	5	1,0	16	3,2	454	100,0	424	93,4	3	0,7	11	2,4	0	0,0	2	0,4	0	0,0	14	3,1
	Grade 3	42	100,0	39	92,9	0	0,0	2	4,8	0	0,0	1	2,4	0	0,0	0	0,0	50	100,0	49	98,0	0	0,0	1	2,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 4	3	100,0	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	100,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Grade 5	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	Missing	23	100,0	1	4,3	0	0,0	0	0,0	0	0,0	0	0,0	1	4,3	21	91,3	10	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	10	100,0

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_resolved.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_resolved_26d_10JAN2022_CHNS.xls
04MAY2022 10:02

Verträglichkeit (Datenschnitt: 10.01.2022)

Post Treatment AE

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any post-treatment AEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	-Total*	-Total	n/a	1783	100,0	136	7,6	1822	100,0	162	8,9
	BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		NEUTROPENIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CARDIAC DISORDER	-Total	n/a	1783	100,0	35	2,0	1822	100,0	37	2,0
		ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2
		ANGINA PECTORIS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		AORTIC VALVE DISEASE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		ATRIAL FIBRILLATION	n/a	1783	100,0	4	0,2	1822	100,0	1	<0.1
		ATRIOVENTRICULAR BLOCK	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		ATRIOVENTRICULAR BLOCK SECOND DEGREE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BRADYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CARDIAC ARREST	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		CARDIAC FAILURE	n/a	1783	100,0	7	0,4	1822	100,0	6	0,3
		CARDIAC FLUTTER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		CARDIOGENIC SHOCK	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CARDIOMYOPATHY	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		CORONARY ARTERY DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		HYPERTENSIVE HEART DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		LEFT ATRIAL DILATATION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		LEFT VENTRICULAR DYSFUNCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		MITRAL VALVE DISEASE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		MITRAL VALVE INCOMPETENCE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		MYOCARDIAL INFARCTION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		MYOCARDIAL ISCHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2
		PALPITATIONS	n/a	1783	100,0	2	0,1	1822	100,0	4	0,2
		PERICARDIAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		PERICARDITIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SINUS BRADYCARDIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
		SINUS TACHYCARDIA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		SUPRAVENTRICULAR TACHYCARDIA	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0
		TACHYCARDIA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		TACHYCARDIA PAROXYSMAL	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		TRICUSPID VALVE DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		VENTRICULAR ARRHYTHMIA	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
		VENTRICULAR EXTRASYSTOLES	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
	GASTROINTESTINAL DISORDER	-Total	n/a	1783	100,0	3	0,2	1822	100,0	1	<0.1
		DIARRHOEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		DYSPEPSIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		HAEMORRHOIDS	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		NAUSEA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		CHEST PAIN	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		PYREXIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INFECTIONS AND INFESTATION	-Total	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		CYTOMEGALOVIRUS INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		UPPER RESPIRATORY TRACT INFECTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		RIB FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	INVESTIGATION	-Total	n/a	1783	100,0	49	2,7	1822	100,0	71	3,9
		EJECTION FRACTION DECREASED	n/a	1783	100,0	47	2,6	1822	100,0	71	3,9

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		ELECTROCARDIOGRAM QT PROLONGED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		HEART RATE INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		WEIGHT INCREASED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	METABOLISM AND NUTRITION DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		DEHYDRATION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		HYPERVOLAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	3	0,2
		ARTHRALGIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		MUSCULOSKELETAL STIFFNESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		PAIN IN EXTREMITY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	47	2,6	1822	100,0	57	3,1
		ACUTE LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
		ADENOCARCINOMA OF COLON	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		ANGIOSARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		APPENDIX CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		B PRECURSOR TYPE ACUTE LEUKAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BASAL CELL CARCINOMA	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3
		BENIGN NEOPLASM OF SKIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BILE DUCT ADENOCARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		BLADDER CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BLADDER TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BOWEN'S DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BRONCHIAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CARDIAC VALVE FIBROELASTOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CHOLANGIOCARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		CLEAR CELL RENAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		COLON CANCER	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		DERMATOFIBROSARCOMA PROTUBERANS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		DIFFUSE LARGE B-CELL LYMPHOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		ENDOMETRIAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2
		ESSENTIAL THROMBOCYTHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		FOLLICULAR LYMPHOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		GANGLIONEUROMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		GASTRIC CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		GASTROINTESTINAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		GLIOBLASTOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		LUNG ADENOCARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		LUNG NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2
		MALIGNANT MELANOMA	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2
		MALIGNANT NEOPLASM OF RENAL PELVIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		MALIGNANT PERITONEAL NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
		MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		METASTATIC MALIGNANT MELANOMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		MYELODYSPLASTIC SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		NEUROENDOCRINE CARCINOMA OF THE SKIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		NEUROENDOCRINE TUMOUR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		OESOPHAGEAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		OVARIAN CANCER	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		OVARIAN EPITHELIAL CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		PANCREATIC CARCINOMA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		PANCREATIC CARCINOMA METASTATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		PROSTATE CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		RECTAL ADENOCARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		RECTAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		RENAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		RETINAL MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SALIVARY GLAND CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SECOND PRIMARY MALIGNANCY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SMALL INTESTINE CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SMALL INTESTINE LEIOMYOSARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SOFT TISSUE SARCOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		SQUAMOUS CELL CARCINOMA OF SKIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		SQUAMOUS CELL CARCINOMA OF THE CERVIX	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		THYROID CANCER	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0
		THYROID NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		UTERINE CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		VULVAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		DIZZINESS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		NEURALGIC AMYOTROPHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		SCIATICA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		SYNCOPE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		ACUTE PULMONARY OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		PLEURAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	VASCULAR DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		HYPERTENSION	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0

* Total number of patients with at least one adverse event
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_ANYAEPT.xls
04MAY2022 9:54

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Any post-treatment related SAEs
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	-Total*	-Total	n/a	1783	100,0	14	0,8	1822	100,0	14	0,8
	BLOOD AND LYMPHATIC SYSTEM DISORDER	-Total	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		NEUTROPENIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	CARDIAC DISORDER	-Total	n/a	1783	100,0	9	0,5	1822	100,0	10	0,5
		ATRIAL FIBRILLATION	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		ATRIOVENTRICULAR BLOCK	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		ATRIOVENTRICULAR BLOCK SECOND DEGREE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		CARDIAC FAILURE	n/a	1783	100,0	7	0,4	1822	100,0	5	0,3
		CARDIOMYOPATHY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		MITRAL VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
	INJURY, POISONING AND PROCEDURAL COMPLICATION	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		RIB FRACTURE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	INVESTIGATION	-Total	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		EJECTION FRACTION DECREASED	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
		ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BOWEN'S DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	NERVOUS SYSTEM DISORDER	-Total	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		NEURALGIC AMYOTROPHY	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		ACUTE PULMONARY OEDEMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		PLEURAL EFFUSION	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

* Total number of patients with at least one adverse event
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AESAEPT.xls
04MAY2022 9:57

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Post-treatment primary cardiac events
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	-Total*	-Total	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2
	CARDIAC DISORDER	-Total	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2
		ACUTE MYOCARDIAL INFARCTION	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		CARDIAC ARREST	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CARDIAC FAILURE	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		CARDIOGENIC SHOCK	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		MITRAL VALVE DISEASE	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

* Total number of patients with at least one adverse event
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AEPCEPT.xls
04MAY2022 9:58

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Post-treatment secondary cardiac events
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	-Total*	-Total	n/a	1783	100,0	8	0,4	1822	100,0	6	0,3
	CARDIAC DISORDER	-Total	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		CARDIAC FAILURE	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
	INVESTIGATION	-Total	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3
		EJECTION FRACTION DECREASED	n/a	1783	100,0	6	0,3	1822	100,0	6	0,3

* Total number of patients with at least one adverse event
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_AESCEPT.xls
04MAY2022 9:59

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Non-breast-related second primary malignancies and myelodysplastic syndrome during post-treatment period
MODEL: Unstratified analysis
STUDY: BO25126
Dichotomous analysis (safety)

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	-Total*	-Total	n/a	1783	100,0	47	2,6	1822	100,0	57	3,1
	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS	-Total	n/a	1783	100,0	47	2,6	1822	100,0	57	3,1
		ACUTE LEUKAEMIA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		ACUTE MYELOID LEUKAEMIA	n/a	1783	100,0	2	0,1	1822	100,0	1	<0.1
		ADENOCARCINOMA OF COLON	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		ANGIOSARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		APPENDIX CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		B PRECURSOR TYPE ACUTE LEUKAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BASAL CELL CARCINOMA	n/a	1783	100,0	3	0,2	1822	100,0	6	0,3
		BENIGN NEOPLASM OF SKIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BILE DUCT ADENOCARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		BLADDER CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BLADDER TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BOWEN'S DISEASE	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		BRONCHIAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CARDIAC VALVE FIBROELASTOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		CHOLANGIOCARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		CLEAR CELL RENAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		COLON CANCER	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		DERMATOFIBROSARCOMA PROTUBERANS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		DIFFUSE LARGE B-CELL LYMPHOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		ENDOMETRIAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	4	0,2
		ESSENTIAL THROMBOCYTHAEMIA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		FOLLICULAR LYMPHOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		GANGLIONEUROMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		GASTRIC CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		GASTROINTESTINAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		GLIOBLASTOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		LENTIGO MALIGNA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		LUNG ADENOCARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		LUNG NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		LUNG NEOPLASM MALIGNANT	n/a	1783	100,0	4	0,2	1822	100,0	3	0,2
		MALIGNANT MELANOMA	n/a	1783	100,0	4	0,2	1822	100,0	4	0,2
		MALIGNANT NEOPLASM OF RENAL PELVIS	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		MALIGNANT PERITONEAL NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	2	0,1
		MENINGIOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		METASTATIC MALIGNANT MELANOMA	n/a	1783	100,0	2	0,1	1822	100,0	0	0,0
		MYELODYSPLASTIC SYNDROME	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		NEUROENDOCRINE CARCINOMA OF THE SKIN	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		NEUROENDOCRINE TUMOUR	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		OESOPHAGEAL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		OVARIAN CANCER	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		OVARIAN EPITHELIAL CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		PANCREATIC CARCINOMA	n/a	1783	100,0	2	0,1	1822	100,0	2	0,1
		PANCREATIC CARCINOMA METASTATIC	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		PROSTATE CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		RECTAL ADENOCARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		RECTAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		RENAL CELL CARCINOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		RETINAL MELANOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1

				PERTUZUMAB (N=1783)				PLACEBO (N=1822)			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
		SALIVARY GLAND CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SECOND PRIMARY MALIGNANCY	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SMALL INTESTINE CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SMALL INTESTINE LEIOMYOSARCOMA	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		SOFT TISSUE SARCOMA	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		SQUAMOUS CELL CARCINOMA OF SKIN	n/a	1783	100,0	1	<0.1	1822	100,0	1	<0.1
		SQUAMOUS CELL CARCINOMA OF THE CERVIX	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		THYROID CANCER	n/a	1783	100,0	3	0,2	1822	100,0	0	0,0
		THYROID NEOPLASM	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0
		TRANSITIONAL CELL CARCINOMA	n/a	1783	100,0	0	0,0	1822	100,0	2	0,1
		UTERINE CANCER	n/a	1783	100,0	0	0,0	1822	100,0	1	<0.1
		VULVAL CANCER	n/a	1783	100,0	1	<0.1	1822	100,0	0	0,0

* Total number of patients with at least one adverse event
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/saf_rsd.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/saf_rsd_26d_10JAN2022_CHNS_NBMSPT.xls
04MAY2022 10:01

Sonstige Analysen (Datenschnitt: 19.12.2016)

Anzahl Zentren, Länder, Regionen

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Number of centers/countries/geographical regions with <10, >=10 patients per arm

	Center				Country				Geographical region (3)			
Category	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	534	100,00%	3634	100,00%	42	100,00%	3634	100,00%	5	100,00%	3634	100,00%
with <10 patients per arm (1)	514	96,30%	3009	82,80%	14	33,30%	171	4,70%	0	0,00%	0	0,00%
with >=10 patients per arm (2)	20	3,70%	625	17,20%	28	66,70%	3463	95,30%	5	100,00%	3634	100,00%

(1): "<10 patients" category if at least one treatment arm has <10 patients. (2): ">=10 patients" category if all treatment arms have >=10 patients.
(3): Geographical regions: USA/Canada, Western Europe, Asia Pacific, Latin America, Other. (4): Number of centers/countries/geographical regions. (5): % of centers/countries/geographical regions compared to overall number.
(6): Number of patients randomized in the corresponding category (e.g. number of patients randomized in centers with <10 patients per arm).
(7): % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_center.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_center_26a_19DEC2016_CHON.xls
30MAR2020 13:27

Sonstige Analysen (Datenschnitt: 19.12.2016)

Todesfälle

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Number of patients who died including primary reason

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
All deaths	72 (4.0%)	80 (4.4%)	152 (4.2%)
Primary reason			
Recurrence of disease	48 (2.7%)	58 (3.2%)	106 (2.9%)
Adverse event	18 (1.0%)	13 (0.7%)	31 (0.9%)
Other	6 (0.3%)	9 (0.5%)	15 (0.4%)

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_dth.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_dth_26a_19DEC2016_CHON.xls
30MAR2020 13:32

Sonstige Analysen (Datenschnitt: 19.12.2016)

Demographische und allgemeine Charakteristika

POPULATION: HR Negative or Node Positive, ITT
ENDPOINT: All patients
STUDY: j25126a
Summary of First Occurrence of an Event
Demographic and Baseline Characteristics by Treatment Regimen
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)	Total (N=3634)
Age (yr)			
n	1811	1823	3634
Mean (SD)	51.5 (10.8)	51.4 (10.7)	51.5 (10.8)
Median	51	51	51
Range	24 - 86	19 - 85	19 - 86
Age (yr)			
n	1811	1823	3634
<35	114 (6.3%)	113 (6.2%)	227 (6.2%)
35-39	141 (7.8%)	133 (7.3%)	274 (7.5%)
40-49	533 (29.4%)	534 (29.3%)	1067 (29.4%)
50-64	793 (43.8%)	824 (45.2%)	1617 (44.5%)
65-74	207 (11.4%)	199 (10.9%)	406 (11.2%)
>=75	23 (1.3%)	20 (1.1%)	43 (1.2%)
Age (yr)			
n	1811	1823	3634
<40	255 (14.1%)	246 (13.5%)	501 (13.8%)
40-64	1326 (73.2%)	1358 (74.5%)	2684 (73.9%)
>=65	230 (12.7%)	219 (12.0%)	449 (12.4%)
Sex			
n	1811	1823	3634
Female	1809 (99.9%)	1817 (99.7%)	3626 (99.8%)
Male	2 (0.1%)	6 (0.3%)	8 (0.2%)
Ethnicity			
n	1811	1823	3634
Hispanic or Latino	37 (2.0%)	31 (1.7%)	68 (1.9%)

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)	Total (N=3634)
Not Hispanic or Latino	322 (17.8%)	296 (16.2%)	618 (17.0%)
Not Reported	1436 (79.3%)	1475 (80.9%)	2911 (80.1%)
Unknown	16 (0.9%)	21 (1.2%)	37 (1.0%)
Race			
n	1806	1821	3627
White	1252 (69.3%)	1255 (68.9%)	2507 (69.1%)
Black	25 (1.4%)	31 (1.7%)	56 (1.5%)
Asian	477 (26.4%)	484 (26.6%)	961 (26.5%)
Other	52 (2.9%)	51 (2.8%)	103 (2.8%)
Weight (kg) at baseline			
n	1804	1817	3621
Mean (SD)	66.9 (14.7)	67.8 (15.1)	67.3 (14.9)
Median	65	65	65
Range	37 - 154	37 - 162	37 - 162
Height (cm) at baseline			
n	1805	1816	3621
Mean (SD)	161.6 (7.0)	161.5 (7.1)	161.5 (7.0)
Median	161	161	161
Range	140 - 183	139 - 188	139 - 188
BMI (WHO Classification)			
n	1804	1816	3620
Underweight	43 (2.4%)	38 (2.1%)	81 (2.2%)
Normal	903 (50.1%)	914 (50.3%)	1817 (50.2%)
Overweight	556 (30.8%)	516 (28.4%)	1072 (29.6%)
Obese	302 (16.7%)	348 (19.2%)	650 (18.0%)
Smoking Status			
n	1811	1823	3634
Ever smoked	498 (27.5%)	526 (28.9%)	1024 (28.2%)
Never smoked	1313 (72.5%)	1297 (71.1%)	2610 (71.8%)
Menopausal Status at Screening			
n	1809	1816	3625
Pre menopausal	873 (48.3%)	885 (48.7%)	1758 (48.5%)

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)	Total (N=3634)
Post menopausal	933 (51.6%)	929 (51.2%)	1862 (51.4%)
Unknown	3 (0.2%)	2 (0.1%)	5 (0.1%)

Ethnicity only recorded for patients at US sites.
BMI (kg/m2): Underweight <18.5; Normal 18.5-24.99; Overweight >=25.0-29.99; Obese >=30.0
Clinical cut-off: 19Dec2016

Program: /opt/BIOSTAT/prod/cdp11450/r25126a/t_dm.sas / Output: /opt/BIOSTAT/prod/cd11450g.pbe/j25126a.pbe/reports/t_dm_26a_TRT1P_IT_CHON.xls
11OCT2017 8:31

Sonstige Analysen (Datenschnitt: 19.12.2016)

DFS Ereignisse mit und ohne Tod

POPULATION: HR negative or node positive ITT
ENDPOINT: DFS (Disease-free survival)
MODEL: --
STUDY: BO25126
DFS events with and without death

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)
All DFS Events		
Total Patients: n (%)	166 (100%)	211 (100%)
Patients with Events		
Contralateral breast cancer	5 (3.0%)	11 (5.2%)
Contralateral or ipsilateral DCIS	3 (1.8%)	8 (3.8%)
Death	16 (9.6%)	14 (6.6%)
Distant recurrence/CNS metastases	100 (60.2%)	121 (57.3%)
Local recurrence	12 (7.2%)	25 (11.8%)
Regional recurrence	8 (4.8%)	11 (5.2%)
Second primary non-breast cancer	22 (13.3%)	21 (10.0%)
All DFS Events without death		
Total Patients: n (%)	150 (100%)	197 (100%)
Patients with Events		
Contralateral breast cancer	5 (3.3%)	11 (5.6%)
Contralateral or ipsilateral DCIS	3 (2.0%)	8 (4.1%)
Distant recurrence/CNS metastases	100 (66.7%)	121 (61.4%)
Local recurrence	12 (8.0%)	25 (12.7%)
Regional recurrence	8 (5.3%)	11 (5.6%)
Second primary non-breast cancer	22 (14.7%)	21 (10.7%)

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_dfsrec.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_dfsrec_26a_19DEC2016_CHON.xls
05AUG2020 16:09

Sonstige Analysen (Datenschnitt: 19.12.2016)

Verteilung der Patienten pro Arm

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Disposition of patients per arm

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
Randomized to study treatment	1811 (100%)	1823 (100%)	3634 (100%)
Received at least one dose of study drug	1794 (99.1%)	1811 (99.3%)	3605 (99.2%)
Completed Pertuzumab/placebo treatment	1533 (84.6%)	1582 (86.8%)	3115 (85.7%)
Discontinued Pertuzumab/placebo treatment	278 (15.4%)	241 (13.2%)	519 (14.3%)
Reason for Pertuzumab/placebo treatment discontinuation			
Adverse event	130 (7.2%)	118 (6.5%)	248 (6.8%)
Death	8 (0.4%)	4 (0.2%)	12 (0.3%)
Pregnancy	1 (<0.1%)	0	1 (<0.1%)
Lost to follow-up	0	1 (<0.1%)	1 (<0.1%)
Non-compliance with study drug	33 (1.8%)	23 (1.3%)	56 (1.5%)
Physician decision	20 (1.1%)	12 (0.7%)	32 (0.9%)
Protocol violation	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Recurrence of disease	20 (1.1%)	28 (1.5%)	48 (1.3%)
Contralateral breast cancer	2 (0.1%)	0	2 (<0.1%)
Withdrawal by subject	38 (2.1%)	35 (1.9%)	73 (2.0%)
Other	25 (1.4%)	17 (0.9%)	42 (1.2%)
Entered follow-up period	1787 (98.7%)	1805 (99.0%)	3592 (98.8%)
Completed follow-up period	0	0	0
Discontinued follow-up period	286 (15.8%)	336 (18.4%)	622 (17.1%)
Reason for discontinuation of follow-up period			

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
Adverse event	7 (0.4%)	11 (0.6%)	18 (0.5%)
Death	13 (0.7%)	14 (0.8%)	27 (0.7%)
Lost to follow-up	14 (0.8%)	15 (0.8%)	29 (0.8%)
Physician decision	4 (0.2%)	6 (0.3%)	10 (0.3%)
Recurrence of disease	117 (6.5%)	159 (8.7%)	276 (7.6%)
Contralateral breast cancer	5 (0.3%)	10 (0.5%)	15 (0.4%)
Withdrawal by subject	113 (6.2%)	114 (6.3%)	227 (6.2%)
Other	13 (0.7%)	7 (0.4%)	20 (0.6%)

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ds.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_ds_26a_19DEC2016_CHON.xls
05AUG2020 16:04

Sonstige Analysen (Datenschnitt: 19.12.2016)

Follow-up time (DFS)

POPULATION: HR negative or node positive ITT
ENDPOINT: Median follow-up duration (efficacy 2)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
n	1811	1823	3634
Median	44,45	44,45	44,45
Min - Max	0.0 - 59.2	0.0 - 58.1	0.0 - 59.2

Follow-up time is calculated as median[(min(data cut date, death date, last date alive, date of the first occurrence of an invasive disease-free survival event including second primary non-breast cancer event or contralateral or ipsilateral DCIS)- randomization date + 1) / 30.4375].
Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_fu_26a_19DEC2016_CHON_EF2DUR.xls
05AUG2020 16:15

Sonstige Analysen (Datenschnitt: 19.12.2016)

Auflistung der Rezidive

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of recurrence

Treatment: PERTUZUMAB (N=1783)

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
208913/2089130068	16APR2015	Distant recurrence	Lung	Radiological	Yes	16APR2015	CARCINOMA.
208922/2089220014	17FEB2015	Second primary malignancy	Thyroid Cancer	Clinical	Yes	17FEB2015	PAPILLARY CARCINOMA
	05SEP2015	Death					
	20AUG2015	Central nervous system	Brain Metastasis	Radiological	No	20AUG2015	
	12AUG2015	Distant recurrence	Bone	Radiological	No	12AUG2015	
	05AUG2015	Distant recurrence	Pleural Effusion	Radiological	No	05AUG2015	
	05AUG2015	Distant recurrence	Liver	Radiological	Yes	05AUG2015	CARCINOMA, METASTATIC
208922/2089220032	09DEC2014	Central nervous system	Brain Metastasis	Radiological	Yes	09DEC2014	CARCINOMA
208922/2089220047	17DEC2015	Regional recurrence	Supraclavicular Lymph Nodes	Clinical	Yes	17DEC2015	INVASIVE DUCTAL CARCINOMA
	21DEC2015	Distant recurrence	Bone	Radiological	No	21DEC2015	
208923/2089230024	31JUL2014	Local recurrence	Breast Surgical Scar	Clinical	Yes	31JUL2014	METASTATIC CARCINOMA
	30OCT2014	Distant recurrence	Pleural Effusion	Radiological	Yes	30OCT2014	MALIGNANT CELLS
	31JUL2014	Local recurrence	Ipsilateral Anterior Chest Wall	Radiological	Yes	31JUL2014	ADENOCARCINOMA
208926/2089260010	14MAR2016	Local recurrence	Ipsilateral Breast	Radiological	Yes	14MAR2016	INVASIVE CARCINOMA OF NO SPECIAL TYPE
209050/2090700003	04MAR2015	Death					
209062/2090620007	07APR2013	Death					
209064/2090640001	03JUN2014	Distant recurrence	Bone	Radiological	No	03JUN2014	
	17MAR2015	Death					
	09JUL2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	09JUL2014	ADENOCARCINOMA
	03JUN2014	Distant recurrence	Lung	Radiological	No	03JUN2014	
209089/2090890019	14OCT2014	Distant recurrence	Lung	Radiological	No	14OCT2014	
	02FEB2015	Death					
	04NOV2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	04NOV2014	POORLY-DIFFERENTIATED ADENOCARCINOMA
	04NOV2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	04NOV2014	
209091/2090910002	23MAY2012	Death					
209091/2090910025	17DEC2013	Death					
209092/2090920019	24JUN2014	Central nervous system	Brain Metastasis	Radiological	No	24JUN2014	
	12DEC2014	Death					
209092/2090920020	30JUN2013	Death					

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
209093/2090930004	16SEP2013	Local recurrence	Ipsilateral Breast	Radiological	Yes	16SEP2013	INFILTRATING DUCTAL CARCINOMA
	11FEB2015	Death					
	03DEC2014	Central nervous system	Brain Metastasis	Radiological	No	03DEC2014	
	30OCT2014	Distant recurrence	Bone	Radiological	No	30OCT2014	
	28JUL2014	Distant recurrence	Liver	Radiological	No	28JUL2014	
209881/2098810020	15FEB2016	Death					
209985/2099850013	02DEC2014	Distant recurrence	Liver	Radiological	No	02DEC2014	
	11FEB2016	Death					
	02DEC2014	Local recurrence	Breast Surgical Scar	Clinical	Yes	02DEC2014	INVASIVE DUCTOLOBULAR CARCINOMA
210267/2102670030	29JUN2015	Distant recurrence	Bone	Radiological	No	29JUN2015	
	12AUG2015	Distant recurrence	Liver	Radiological	Yes	12AUG2015	METASTATIC BREAST CANCER (LUMINALNY B, HER-2 POSIT
210267/2102670039	10JUN2014	Second primary malignancy	Advanced Gastrointestinal Malignancy	Clinical	Yes	10JUN2014	ADVANCED MALIGNANCY FROM GI TRACT
	05MAR2015	Death					
210267/2102670043	30MAY2016	Local recurrence	Skin Or Soft Tissue Within The Local Area	Radiological	Yes	30MAY2016	INVASIVUM CANCER
210267/2102670046	23NOV2015	Central nervous system	Brain Metastasis	Radiological	No	23NOV2015	
210267/2102670049	30APR2014	Central nervous system	Brain Metastasis	Radiological	No	30APR2014	
210267/2102670061	16MAR2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Clinical	Yes	16MAR2016	METASTASIS BREAST CANCER
210474/2104740003	13JUN2014	Local recurrence	Breast Surgical Scar	Clinical	No	13JUN2014	
230712/2307120012	18OCT2016	Distant recurrence	Bone	Radiological	No	18OCT2016	
	18OCT2016	Regional recurrence	Supraclavicular Lymph Nodes	Radiological	No	18OCT2016	
	18OCT2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	18OCT2016	
	18OCT2016	Distant recurrence	Lung	Radiological	No	18OCT2016	
	18OCT2016	Distant recurrence	Liver	Radiological	Yes	18OCT2016	TISSUE
230740/2307400003	06MAY2014	Distant recurrence	Bone	Radiological	No	06MAY2014	
230804/2308040003	12SEP2014	Central nervous system	Brain Metastasis	Radiological	Yes	12SEP2014	CARCINOMA
230814/2308140006	02MAY2014	Second primary malignancy	Urothelial Carcinoma	Clinical	Yes	02MAY2014	HIGH GRADE PAPILLARY UROTHELIAL CARCINOMA
230824/2308240002	30OCT2015	Distant recurrence	Bone	Radiological	No	30OCT2015	
	30OCT2015	Regional recurrence	Internal Mammary Lymph Nodes	Radiological	No	30OCT2015	
	30OCT2015	Local recurrence	Skin Or Soft Tissue Within The Local Area	Radiological	No	30OCT2015	
230853/2308530002	19FEB2015	Distant recurrence	Lung	Radiological	No	19FEB2015	
	02SEP2016	Death					
	12MAY2016	Central nervous system	Brain Metastasis	Radiological	No	12MAY2016	
	14APR2015	Distant recurrence	Bone	Radiological	No	14APR2015	
	25FEB2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	25FEB2015	
230860/2308600004	29NOV2016	Distant recurrence	Bone	Radiological	No	29NOV2016	
230860/2308600008	24SEP2013	Distant recurrence	Bone	Radiological	No	24SEP2013	
230860/2308600010	17FEB2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Clinical	Yes	17FEB2014	CYTOLOGIC REPORT FNA NECK NODE

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
230861/2308610008	30SEP2014	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	30SEP2014	NODULAR BASAL CELL
	06JUN2016	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	06JUN2016	INFILTRATIVE AND NODULAR BASAL CELL
230865/2308650013	16AUG2013	Death					
230869/2308690006	22AUG2013	Second primary malignancy	Lung Cancer	Radiological	Yes	22AUG2013	SQUAMOUS CELL CARCINOMA OF THE LUNG
	06MAY2014	Death					
230872/2308720012	16FEB2014	Central nervous system	Brain Metastasis	Radiological	Yes	16FEB2014	METASTATIC ADENOCARCINOMA
230876/2308760002	22MAY2014	Central nervous system	Brain Metastasis	Radiological	No	22MAY2014	
	21DEC2014	Death					
	23MAY2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	23MAY2014	
	23MAY2014	Distant recurrence	Lung	Radiological	No	23MAY2014	
	22MAY2014	Distant recurrence	Bone	Radiological	No	22MAY2014	
230876/2308760004	24AUG2015	Second primary malignancy	Renal Cell Carcinoma	Radiological	Yes	24AUG2015	GRADE 3 CLEAR CELL RENAL CA
230878/2308780028	18NOV2014	Local recurrence	Skin Or Soft Tissue Within The Local Area	Clinical	Yes	18NOV2014	IDC GRADE 2 IN DERMIS AND SUBCUTANEOUS FAT,CK7 +VE
230878/2308780029	13JUL2015	Non-invasive disease	Melanoma	Clinical	Yes	13JUL2015	MELANOMA IN SITU
230959/2309590044	01FEB2016	Distant recurrence	Liver	Radiological	Yes	01FEB2016	ADENOCARCINOMA
	11FEB2016	Distant recurrence	Lung	Radiological	No	11FEB2016	
	11FEB2016	Distant recurrence	Bone	Radiological	No	11FEB2016	
231193/2311930024	15DEC2013	Central nervous system	Brain Metastasis	Radiological	No	15DEC2013	
	13JAN2015	Death					
	17DEC2013	Distant recurrence	Bone	Radiological	No	17DEC2013	
231248/2312480029	07OCT2015	Distant recurrence	Liver	Radiological	Yes	07OCT2015	INVASIV DUCTAL CANCER
	10APR2016	Death					
231267/2312670008	02JUL2014	Distant recurrence	Lung	Radiological	No	02JUL2014	
	03DEC2015	Death					
	03MAR2015	Central nervous system	Brain Metastasis	Radiological	No	03MAR2015	
231267/2312670044	27DEC2013	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	27DEC2013	CARCINOMA IN SITU WITH MICROINVASION
231270/2312700013	23MAR2015	Distant recurrence	Liver	Radiological	Yes	23MAR2015	HEPATIC LOCALIZATION RE+++ RP - HER +++
231270/2312700017	08JAN2016	Central nervous system	Brain Metastasis	Radiological	No	08JAN2016	
231271/2312710032	11DEC2014	Distant recurrence	Bone	Radiological	No	11DEC2014	
231272/2312720038	03MAY2016	Second primary malignancy	Melanoma	Clinical	Yes	03MAY2016	MELANOMA
	02DEC2016	Death					
231289/2312890010	05JUN2015	Distant recurrence	Adrenal	Radiological	No	05JUN2015	
	16AUG2015	Death					
	21JUL2015	Central nervous system	Brain Metastasis	Radiological	No	21JUL2015	
	05JUN2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	05JUN2015	
	05JUN2015	Distant recurrence	Pleural Effusion	Radiological	No	05JUN2015	
	05JUN2015	Distant recurrence	Lung	Radiological	No	05JUN2015	
	05JUN2015	Distant recurrence	Liver	Radiological	No	05JUN2015	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	05JUN2015	Distant recurrence	Bone	Radiological	No	05JUN2015	
231300/2313000003	29APR2014	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	29APR2014	LEFT CARCINOMA IN SITU
231302/2313020003	09DEC2013	Central nervous system	Brain Metastasis	Radiological	No	09DEC2013	
	19FEB2015	Death					
231303/2313030008	07JUN2013	Distant recurrence	Bone	Radiological	No	07JUN2013	
	27MAY2014	Death					
	02SEP2013	Central nervous system	Brain Metastasis	Radiological	No	02SEP2013	
231303/2313030014	14NOV2016	Distant recurrence	Lung	Radiological	Yes	14NOV2016	BREAST CANCER ER+, PR+, HER2+
231304/2313040003	23MAR2016	Distant recurrence	Liver	Radiological	No	23MAR2016	
	20APR2016	Distant recurrence	Bone	Radiological	No	20APR2016	
	24MAR2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	24MAR2016	INVASIVE NOS
231304/2313040008	17OCT2014	Second primary malignancy	Sigmoidal Cancer	Radiological	Yes	17OCT2014	ADENOCARCINOMA
231307/2313070008	23OCT2014	Central nervous system	Brain Metastasis	Radiological	No	23OCT2014	
231411/2314110020	15JUN2015	Second primary malignancy	Biliar Adenocarcinoma	Radiological	Yes	15JUN2015	ADENOCARCINOMA
	10JUN2016	Death					
	02OCT2015	Distant recurrence	Liver	Radiological	Yes	02OCT2015	DUCTAL INVASIVE
231434/2314340011	11MAY2015	Distant recurrence	Pleural Effusion	Radiological	Yes	11MAY2015	BREASTCARCINOMA
	28AUG2016	Death					
231434/2314340012	01JAN2015	Central nervous system	Brain Metastasis	Radiological	Yes	01JAN2015	METASTASIS MAMMACARCINOMA
	24MAR2015	Death					
231455/2314550011	21AUG2015	Distant recurrence	Liver	Radiological	No	21AUG2015	
	10DEC2015	Death					
	21AUG2015	Distant recurrence	Spleen; Adrenal Gland	Radiological	No	21AUG2015	
	21AUG2015	Distant recurrence	Lung	Radiological	No	21AUG2015	
231465/2314650012	24NOV2014	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	24NOV2014	INVASIV DUCTAL
231465/2314650017	22JUL2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	22JUL2014	LYMPH NODE METASTASIS
231474/2314740007	15MAY2013	Death					
231474/2314740009	13NOV2014	Central nervous system	Brain Metastasis	Radiological	No	13NOV2014	
	26AUG2016	Death					
231539/2315390002	27NOV2013	Central nervous system	Brain Metastasis	Radiological	No	27NOV2013	
231621/2316210017	14OCT2015	Distant recurrence	Bone	Radiological	No	14OCT2015	
231621/2316210033	21OCT2016	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	21OCT2016	INVASIVE LOBULAR CARCINOMA
231625/2316250008	12FEB2016	Distant recurrence	Lung	Radiological	Yes	12FEB2016	METASTASIS OF DUCTAL BREAST CARCINOMA
231625/2316250015	21NOV2014	Central nervous system	Brain Metastasis	Radiological	Yes	21NOV2014	DUCTAL ADENOCARCINOMA
231628/2316280015	18OCT2013	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	18OCT2013	ER +/ PR −, HER2 −, INVASIVE DUCTAL CARCINOMA
231630/2316300030	27JUN2016	Second primary malignancy	Pulmonary Cancer	Radiological	No	27JUN2016	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
231634/2316340003	24FEB2014	Distant recurrence	Bone	Radiological	No	24FEB2014	
	27FEB2014	Central nervous system	Brain Metastasis	Radiological	No	27FEB2014	
231662/2316620009	21JUL2014	Death					
231754/2317540003	12JUL2013	Central nervous system	Brain Metastasis	Radiological	No	12JUL2013	
	18APR2014	Death					
231839/2318390011	25AUG2015	Distant recurrence	Liver	Radiological	Yes	25AUG2015	APOCRINE BREAST CANCER
	28AUG2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	28AUG2015	
	28AUG2015	Distant recurrence	Lung	Radiological	No	28AUG2015	
	28AUG2015	Distant recurrence	Bone	Radiological	No	28AUG2015	
232087/2320870002	28AUG2012	Non-invasive disease	Ipsilateral Ductal Carcinoma In Situ	Radiological	Yes	28AUG2012	DCIS
232093/2320930002	09APR2014	Regional recurrence	Infraclavicular Lymph Nodes	Radiological	No	09APR2014	
	09APR2014	Regional recurrence	Supraclavicular Lymph Nodes	Radiological	Yes	09APR2014	NA
	09APR2014	Regional recurrence	Internal Mammary Lymph Nodes	Radiological	No	09APR2014	
232097/2320970006	03SEP2015	Second primary malignancy	Melanoma (Left Foot)	Clinical	Yes	03SEP2015	MELANOM DORSALIS PEDIS SIN., BR. 0.4 MM, AJCC IA
232102/2321020003	19NOV2014	Distant recurrence	Liver	Radiological	No	19NOV2014	
	11FEB2015	Death					
232109/2321090001	07JUL2015	Distant recurrence	Lung	Radiological	No	07JUL2015	
232191/2321910003	07NOV2016	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	07NOV2016	SOLID BASAL CELL CARCINOMA
232196/2321960001	10FEB2016	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	10FEB2016	DUCTAL CARCINOMA IN-SITU (DCIS)
232262/2322620007	22SEP2016	Central nervous system	Brain Metastasis	Radiological	No	22SEP2016	
	24NOV2016	Death					
232273/2322730022	17SEP2015	Central nervous system	Brain Metastasis	Radiological	No	17SEP2015	
232273/2322730031	17JUL2014	Distant recurrence	Bone	Radiological	No	17JUL2014	
	17JUL2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	17JUL2014	
	17JUL2014	Distant recurrence	Peritoneum	Radiological	No	17JUL2014	
232300/2323000026	24JAN2014	Distant recurrence	Bone	Clinical	No	24JAN2014	
	28AUG2014	Death					
232324/2323240036	31MAR2014	Distant recurrence	Bone	Radiological	No	31MAR2014	
	05JUN2014	Central nervous system	Brain Metastasis	Radiological	No	05JUN2014	
232324/2323240046	15OCT2015	Distant recurrence	Lung	Radiological	Yes	15OCT2015	METASTATIC ADENOCARCINOMA
232330/2323300006	15JUL2014	Second primary malignancy	Locally Advanced Pancreatic Cancer	Radiological	No	15JUL2014	
232331/2323310002	13JAN2015	Central nervous system	Brain Metastasis	Radiological	Yes	13JAN2015	METASTASIS FROM BREAST CANCER
232334/2323340003	05SEP2013	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	05SEP2013	CARCINOM
232335/2323350003	25FEB2016	Death					
232338/2323380007	23DEC2013	Distant recurrence	Pleural Effusion	Radiological	Yes	23DEC2013	ADENOCARCINOMA

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	06JUN2014	Death					
232338/2323380012	22MAR2016	Distant recurrence	Bone	Clinical	No	22MAR2016	
232343/2323430001	25SEP2015	Central nervous system	Brain Metastasis	Radiological	No	25SEP2015	
232393/2323930004	09NOV2014	Central nervous system	Brain Metastasis	Radiological	No	09NOV2014	
232448/2324480003	30APR2013	Death					
232450/2324500006	04FEB2016	Distant recurrence	Lung	Radiological	Yes	04FEB2016	DUCTAL INFILTRANTE INFILTRATING
232474/2324740004	19OCT2015	Central nervous system	Brain Metastasis	Radiological	No	19OCT2015	
232497/2324970004	02JUL2015	Distant recurrence	Liver	Radiological	No	02JUL2015	
	31JUL2015	Death					
232508/2325080007	03JUN2014	Central nervous system	Brain Metastasis	Radiological	No	03JUN2014	
	21OCT2014	Death					
	03JUN2014	Distant recurrence	Lung	Radiological	Yes	03JUN2014	LOW DIFFERENTIATED CARCINOMA
	03JUN2014	Distant recurrence	Liver	Radiological	No	03JUN2014	
232542/2325420014	30JAN2015	Central nervous system	Brain Metastasis	Radiological	Yes	30JAN2015	METASTATIC ADENOCARCINOMA
232554/2325540003	29OCT2013	Local recurrence	Ipsilateral Breast	Radiological	Yes	29OCT2013	INVASIVE DUCTAL MAMMACARCINOMA
	01OCT2014	Death					
	30SEP2014	Central nervous system	Meningitis Carcinomatosa	Radiological	No	30SEP2014	
	30SEP2014	Central nervous system	Brain Metastasis	Radiological	No	30SEP2014	
	03APR2014	Distant recurrence	Lung	Radiological	No	03APR2014	
	03APR2014	Distant recurrence	Liver	Radiological	No	03APR2014	
	20DEC2013	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	20DEC2013	INVASIVE DUCTAL MAMMACARCINOMA
232562/2325620017	01JAN2016	Distant recurrence	Bone	Radiological	Yes	01JAN2016	ADENOCARCINOMA
	29AUG2016	Death					
	27FEB2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	27FEB2016	
232585/2325850008	03MAR2016	Local recurrence	Breast Surgical Scar	Radiological	Yes	03MAR2016	DUCTAL INVASIVE
232586/2325860001	21OCT2014	Distant recurrence	Lung	Radiological	No	21OCT2014	
232615/2326150011	30NOV2015	Central nervous system	Brain Metastasis	Radiological	Yes	30NOV2015	BREAST CANCER
232626/2326260006	11JUL2013	Non-invasive disease	Cervical Melanoma In Situ	Clinical	Yes	11JUL2013	IN SITU
232638/2326380002	08NOV2016	Distant recurrence	Bone	Radiological	No	08NOV2016	
232650/2326500009	21NOV2016	Distant recurrence	Bone	Radiological	No	21NOV2016	
232655/2326550003	06NOV2015	Non-invasive disease	Right Carcinoma In Situ	Radiological	Yes	06NOV2015	CARCINOMA IN SITU
232668/2331030012	31JAN2014	Distant recurrence	Liver	Radiological	Yes	31JAN2014	ADENOCARCINOMA EPITHELIAL PHENOTYPE, FROM METASTAT
	10OCT2015	Death					
	10MAR2015	Central nervous system	Brain Metastasis	Radiological	No	10MAR2015	
232678/2326780001	04JAN2016	Distant recurrence	Bone	Radiological	No	04JAN2016	
	24MAY2016	Death					
233617/2336170003	12DEC2014	Distant recurrence	Mediastinum Soft Tissue, Soft Tissue	Radiological	No	12DEC2014	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	12DEC2014	Regional recurrence	Skin Or Soft Tissue Within The Regional Area	Radiological	No	12DEC2014	
	12DEC2014	Regional recurrence	Infraclavicular Lymph Nodes	Radiological	No	12DEC2014	
	12DEC2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	12DEC2014	
233710/2337100001	05JUN2016	Death					
233710/2337100002	13AUG2013	Local recurrence	Breast Surgical Scar	Radiological	Yes	13AUG2013	RECURRENT INVASIVE DUCTAL CARCINOMA
234310/2343100026	12JUN2014	Central nervous system	Brain Metastasis	Radiological	No	12JUN2014	
	02JUL2015	Death					
234312/2343120021	07AUG2014	Central nervous system	Brain Metastasis	Radiological	Yes	07AUG2014	LOBULAR ADENOCARCINOMA
	05NOV2014	Death					
234314/2343140011	11DEC2013	Distant recurrence	Lung	Radiological	No	11DEC2013	
	30MAY2014	Death					
234465/2344650003	19MAR2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	19MAR2015	ADENOCARCINOMA
	14DEC2015	Death					
	19MAR2015	Regional recurrence	Supraclavicular Lymph Nodes	Radiological	No	19MAR2015	
234616/2346160010	24SEP2015	Non-invasive disease	Carcinoma In Situ Of The Cervix	Clinical	Yes	24SEP2015	SQUAMOUS
234618/2346180008	03MAY2015	Death					
235413/2354130008	19MAY2014	Local recurrence	Breast Surgical Scar	Clinical	Yes	19MAY2014	RECURRENT INVASIVE DUCTAL CARCINOMA
236283/2362830003	23JUN2014	Second primary malignancy	Melanoma	Clinical	Yes	23JUN2014	INVASIVE MALIGNANT MELANOMA
237285/2372850008	08MAY2015	Second primary malignancy	Glioblastoma	Radiological	Yes	08MAY2015	HIGH GRADE GLIOMA
	04JUL2015	Death					
237287/2372870023	23JUN2014	Regional recurrence	Supraclavicular Lymph Nodes	Clinical	Yes	23JUN2014	METASTATIC CARCINOMA
	12FEB2016	Death					
	01JUL2015	Central nervous system	Brain Metastasis	Radiological	No	01JUL2015	
	08JUN2015	Distant recurrence	Lung	Radiological	No	08JUN2015	
	08JUN2015	Distant recurrence	Bone	Radiological	No	08JUN2015	
237290/2372900014	08JAN2013	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	08JAN2013	METASTATIC GRADE III BREAST CANCER
237290/2372900030	22SEP2015	Central nervous system	Brain Metastasis	Radiological	Yes	22SEP2015	METASTATIC CARCINOMA
237290/2372900045	12DEC2014	Distant recurrence	Bone	Radiological	No	12DEC2014	
	30AUG2016	Death					
	12DEC2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	No	12DEC2014	
	12DEC2014	Regional recurrence	Internal Mammary Lymph Nodes	Radiological	No	12DEC2014	
238639/2386390006	25JAN2016	Central nervous system	Brain Metastasis	Radiological	No	25JAN2016	
	25JAN2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	25JAN2016	
	25JAN2016	Distant recurrence	Lung	Radiological	Yes	25JAN2016	BREAST CA
	25JAN2016	Distant recurrence	Liver	Radiological	No	25JAN2016	
238744/2387440006	30JUN2015	Central nervous system	Brain Metastasis	Radiological	Yes	30JUN2015	ER/PR NEGATIVE HER2 POSITIVE METASTATIC CARCINOMA
	27OCT2016	Death					
239233/2392330005	06JUN2013	Central nervous system	Brain Metastasis	Radiological	Yes	06JUN2013	CONSISTENT WITH BREAST PRIMARY.

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	28JAN2014	Distant recurrence	Liver	Radiological	No	28JAN2014	
243805/2438050002	11SEP2015	Second primary malignancy	Lung Cancer	Radiological	Yes	11SEP2015	SQUAMOUS CELL CARCINOMA
243808/2438080015	31AUG2015	Distant recurrence	Liver	Radiological	No	31AUG2015	
	19APR2016	Death					
	31AUG2015	Distant recurrence	Multiple Lymdh Nodes	Radiological	No	31AUG2015	
	31AUG2015	Distant recurrence	Lung	Radiological	No	31AUG2015	
243823/2438230001	25DEC2013	Second primary malignancy	Acute Myelogenous Leukemia	Clinical	No	25DEC2013	
	21FEB2014	Death					
243828/2438280008	29SEP2014	Second primary malignancy	Tongue Cancer	Clinical	Yes	29SEP2014	SQUAMOUS CELL CARCINOMA, INVASSIVE
	27OCT2015	Death					
	02MAR2015	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	02MAR2015	ADEQUATE,MALIGNANT,INTRADUCTAL CARCINOMA
243829/2438290014	19MAY2015	Central nervous system	Brain Metastasis	Radiological	No	19MAY2015	
	19JUN2015	Death					
	21MAY2015	Distant recurrence	Bone	Radiological	No	21MAY2015	
	19MAY2015	Central nervous system	Meningitis Carcinomatosa	Radiological	No	19MAY2015	
243831/2438310012	09DEC2015	Distant recurrence	Bone	Radiological	No	09DEC2015	
	09DEC2015	Regional recurrence	Infraclavicular Lymph Nodes	Radiological	No	09DEC2015	
	09DEC2015	Local recurrence	Ipsilateral Anterior Chest Wall	Radiological	Yes	09DEC2015	ADENOCARCINOMA
243833/2438330004	10OCT2016	Death					
243842/2438420003	02AUG2013	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	02AUG2013	METASTATIC CARCINOMA OF THE RIGHT AXILLARY LYMPH N
243843/2438430018	18NOV2014	Central nervous system	Brain Metastasis	Radiological	No	18NOV2014	
243844/2438440007	07JUN2016	Local recurrence	Ipsilateral Breast	Clinical	Yes	07JUN2016	INVASIVE DUCTAL CARCINOMA
243974/2439740005	16DEC2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Clinical	Yes	16DEC2014	CARCINOMA
243979/2439790002	19FEB2014	Second primary malignancy	Invasive Malignant Melanoma	Clinical	Yes	19FEB2014	MELANOMA (ARISEN IN ASSOCIATION WITH A NEVUS)
	17JUN2015	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	17JUN2015	BCC WITH EXCORIATION, NODULAR, INFILTRATIVE & SUPE
246607/2466070001	28JAN2014	Central nervous system	Brain Metastasis	Radiological	No	28JAN2014	
	29JUL2014	Death					
	30JAN2014	Distant recurrence	Bone	Radiological	No	30JAN2014	
246908/2469080007	23SEP2014	Distant recurrence	Liver	Radiological	No	23SEP2014	
	10JUN2015	Death					
	03FEB2015	Central nervous system	Brain Metastasis	Radiological	No	03FEB2015	
	23SEP2014	Distant recurrence	Lung	Radiological	No	23SEP2014	
247070/2470700001	17JUN2015	Central nervous system	Brain Metastasis	Radiological	No	17JUN2015	
247070/2470700013	17DEC2013	Distant recurrence	Bone	Radiological	No	17DEC2013	
250537/2505370015	07JUL2015	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	No	07JUL2015	
250538/2505380006	02FEB2016	Second primary malignancy	Acute Leukemia	Clinical	Yes	02FEB2016	AMAL
250544/2505440007	15JUL2015	Distant recurrence	Lung	Radiological	No	15JUL2015	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
250546/2505460002	17FEB2014	Distant recurrence	Bone	Radiological	No	17FEB2014	
	01AUG2015	Death					
250651/2506510003	26APR2014	Second primary malignancy	Acute Myelogenous Leukemia(Therapy Related Leukemia)	Clinical	Yes	26APR2014	ACUTE MYELOGENOUS LEUKEMIA
	12FEB2015	Death					
250840/2508400003	13JAN2015	Second primary malignancy	Intracranial Space Occupying	Clinical	Yes	13JAN2015	CENTRAL NEUROCYTOMA
250841/2508410060	30SEP2013	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Clinical	Yes	30SEP2013	METASTATIC POORLY DIFFERENTIATED ADENOCARCINOMA
	18AUG2014	Distant recurrence	Lung	Radiological	No	18AUG2014	
250841/2508410081	03NOV2015	Distant recurrence	Lung	Radiological	No	03NOV2015	
	09AUG2016	Death					
	11DEC2015	Contralateral breast cancer	Contralateral Breast Cancer	Clinical	Yes	11DEC2015	INFILTRATIVE CARCINOMA
	20NOV2015	Distant recurrence	Liver	Radiological	Yes	20NOV2015	HEPATIC METASTASES
	19NOV2015	Central nervous system	Brain Metastasis	Radiological	No	19NOV2015	
	18NOV2015	Distant recurrence	Bone	Radiological	No	18NOV2015	
250841/2508410111	26MAR2015	Distant recurrence	Lung	Clinical	No	26MAR2015	
250846/2508460012	21FEB2014	Central nervous system	Brain Metastasis	Radiological	No	21FEB2014	
	10OCT2014	Death					
250846/2508460019	10FEB2015	Distant recurrence	Lung	Radiological	No	10FEB2015	
	10FEB2015	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	No	10FEB2015	
250846/2508460021	15OCT2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	15OCT2015	UNKNOWN
250848/2508480024	01JAN2016	Death					
250849/2508490002	21APR2016	Second primary malignancy	The Left Lung Upper Lobe Carcinoma	Radiological	Yes	21APR2016	ADENOCARCINOMA
250852/2508520001	10NOV2015	Distant recurrence	Lung	Radiological	No	10NOV2015	

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_rec.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_rec_26a_19DEC2016_CHNS.xls
30MAR2020 15:29

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of recurrence

Treatment: PLACEBO (N=1822)

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
208912/2089120010	08AUG2014	Regional recurrence	Skin Or Soft Tissue Within The Regional Area	Clinical	Yes	08AUG2014	CARCINOMA
208912/2089120016	04FEB2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	04FEB2015	METASTATIC CARCINOMA
208913/2089130061	29OCT2014	Distant recurrence	Bone	Radiological	Yes	29OCT2014	CONSISTENT WITH METASTATIC CARCINOMA FROM BREAST
208915/2089150007	14JAN2014	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	14JAN2014	INVASIVE DUCTAL CARCINOMA
208917/2089170013	21FEB2013	Central nervous system	Brain Metastasis	Radiological	No	21FEB2013	
	20JUL2013	Death					
208922/2089220003	17JUL2015	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	17JUL2015	INVASIVE CARCINOMA
208922/2089220015	03MAR2014	Local recurrence	Skin Or Soft Tissue Within The Local Area	Clinical	Yes	03MAR2014	CARCINOMA
208922/2089220033	27FEB2014	Distant recurrence	Lung	Radiological	No	27FEB2014	
208923/2089230048	12JAN2016	Second primary malignancy	Lung Cancer	Radiological	Yes	12JAN2016	SQUAMOUS CELL CARCINOMA
	09JUL2016	Death					
208925/2089250012	11NOV2014	Distant recurrence	Bone	Radiological	Yes	11NOV2014	METASTATIC CARCINOMA.
208926/2089260006	17FEB2015	Distant recurrence	Liver	Radiological	No	17FEB2015	
	03MAR2015	Distant recurrence	Bone	Radiological	No	03MAR2015	
	17FEB2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	17FEB2015	
209046/2090460001	20MAY2013	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	20MAY2013	SQUAMOUS CELL
209047/2090470004	23NOV2015	Central nervous system	Brain Metastasis	Radiological	Yes	23NOV2015	ER POSITIVE
209057/2090570007	07APR2015	Central nervous system	Brain Metastasis	Radiological	No	07APR2015	
	13APR2015	Distant recurrence	Lung	Radiological	Yes	13APR2015	TUMOUR ENTIRELY CONSISTENT WITH METASTATIC BREAST
209059/2090590007	01APR2014	Local recurrence	Breast Surgical Scar	Clinical	Yes	01APR2014	BREAST DUCTAL CARCINOMA
	01APR2014	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	01APR2014	BREAST ADENOCARCINOMA
209062/2090620008	02AUG2013	Non-invasive disease	Contralateral Lobular Carcinoma In Situ	Clinical	Yes	02AUG2013	LCIS
	02AUG2013	Non-invasive disease	Ipsilateral Lobular Carcinoma In Situ	Clinical	Yes	02AUG2013	LCIS
209064/2090640009	14JAN2014	Distant recurrence	Liver	Radiological	No	14JAN2014	
	14JAN2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	14JAN2014	
	14JAN2014	Distant recurrence	Lung	Radiological	No	14JAN2014	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
209070/2090700005	01JUL2016	Central nervous system	Brain Metastasis	Radiological	No	01JUL2016	
	04JUL2016	Distant recurrence	Lung	Radiological	Yes	04JUL2016	ADENOCARCINOMA
209072/2090720003	12MAY2014	Non-invasive disease	Contralateral Lobular Carcinoma In Situ	Clinical	Yes	12MAY2014	PLEOMORPHIC LCIS
209072/2090720013	26MAR2015	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	26MAR2015	FOREHEAD BCC NODULAR TYPE; R HAND SCC WELL DIFF
209089/2090890017	18MAY2015	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	18MAY2015	DCIS(NON-COMEDO PATTERN)
209089/2090890020	20SEP2013	Death					
209091/2090910008	04SEP2015	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	04SEP2015	DUCTAL CACINOMA IN SITU
209091/2090910014	06MAR2013	Death					
209302/2093020007	22SEP2014	Distant recurrence	Bone	Radiological	No	22SEP2014	
	07OCT2014	Central nervous system	Brain Metastasis	Radiological	No	07OCT2014	
	22SEP2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	22SEP2014	
	22SEP2014	Distant recurrence	Lung	Radiological	Yes	22SEP2014	NOT SPECIFIED
	22SEP2014	Distant recurrence	Liver	Radiological	Yes	22SEP2014	CARCINOMA, G1, HER-2 3+, ER AND PGR 0%
209302/2093020020	10OCT2014	Distant recurrence	Left Ovary	Radiological	Yes	10OCT2014	POORLY DIFFERENTIATED CARCINOMA OF THE BREAST
209302/2093020026	09OCT2014	Distant recurrence	Bone	Radiological	Yes	09OCT2014	INVASIVE CARCINOMA OF THE BREAST
	16OCT2014	Central nervous system	Brain Metastasis	Radiological	No	16OCT2014	
209881/2098810023	25JUL2014	Second primary malignancy	Skin Melanoma	Clinical	Yes	25JUL2014	MELANOMA SUPERFICIAL WITH SIGNS OF INITIAL DERMAL
209994/2099940003	14DEC2013	Death					
209998/2099980021	12JAN2015	Central nervous system	Brain Metastasis	Clinical	Yes	12JAN2015	ADENOCARCINOMA
209999/2099990009	03OCT2014	Distant recurrence	Bone	Radiological	No	03OCT2014	
	20OCT2015	Death					
	03OCT2014	Distant recurrence	Lung	Radiological	No	03OCT2014	
	03OCT2014	Distant recurrence	Liver	Radiological	No	03OCT2014	
210263/2102630004	09AUG2013	Distant recurrence	Lung	Radiological	No	09AUG2013	
	29FEB2016	Death					
210266/2102660007	11JUL2014	Local recurrence	Skin Or Soft Tissue Within The Local Area	Clinical	Yes	11JUL2014	DUCTAL CARCINOMA
210266/2102660010	15FEB2016	Central nervous system	Brain Metastasis	Radiological	Yes	15FEB2016	METASTATIC DUCTAL CARCINOMA
210267/2102670011	21JAN2014	Distant recurrence	Left Ovary	Clinical	Yes	21JAN2014	METASTATIC LESIONS OF BREAST CANCER
	19NOV2015	Death					
210267/2102670012	16JUN2016	Distant recurrence	Lung	Radiological	No	16JUN2016	
	20JUN2016	Distant recurrence	Liver	Radiological	No	20JUN2016	
210267/2102670021	08SEP2014	Distant recurrence	Pleural Effusion	Clinical	No	08SEP2014	
	18JUN2015	Death					
	22SEP2014	Distant recurrence	Lung	Radiological	No	22SEP2014	
	22SEP2014	Distant recurrence	Bone	Radiological	No	22SEP2014	
210267/2102670058	29OCT2014	Distant recurrence	Ovariorum	Radiological	Yes	29OCT2014	CARCINOMA E MAMMAE METASTATICUM
	15MAY2015	Death					

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
210361/2103610004	19JUN2012	Death					
210361/2103610006	27AUG2015	Second primary malignancy	Small Bowel Carcinoma	Clinical	Yes	27AUG2015	SMALL BOWEL CARCINOMA
210363/2103630014	20SEP2016	Second primary malignancy	Primary Peritoneal Carcinoma	Clinical	Yes	20SEP2016	SEROUS, LOW GRADE
210363/2103630017	18APR2013	Second primary malignancy	Pancreatic Carcinom	Clinical	Yes	18APR2013	ADENOCARCINOM
	15APR2014	Death					
210474/2104740002	17FEB2016	Local recurrence	Breast Surgical Scar	Radiological	Yes	17FEB2016	DUCTAL INVASIVE
210474/2104740004	24MAY2016	Non-invasive disease	Ipsilateral Ductal Carcinoma In Situ	Clinical	Yes	24MAY2016	DCIS
210474/2104740012	03FEB2015	Regional recurrence	Supraclavicular Lymph Nodes	Radiological	Yes	03FEB2015	METASTATIS BREAST CANCER
210526/2105260013	30NOV2013	Central nervous system	Brain Metastasis	Radiological	No	30NOV2013	
	30JUL2014	Death					
230740/2307400004	27JUN2014	Central nervous system	Brain Metastasis	Radiological	Yes	27JUN2014	ADENOCARCINOMA
230804/2308040004	30MAY2016	Distant recurrence	Bone	Radiological	No	30MAY2016	
230805/2308050023	24MAR2016	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	24MAR2016	MICROINVASIVE DUCTAL CARCINOMA
	24MAR2016	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	24MAR2016	DCIS WITH FOCUS OF MICROINVASION
230810/2308100005	25JAN2013	Distant recurrence	Liver	Radiological	No	25JAN2013	
	04JUL2014	Death					
230818/2308180001	22MAY2014	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Clinical	Yes	22MAY2014	LOW GRADE DCIS
230850/2308500014	12JUN2014	Central nervous system	Brain Metastasis	Radiological	No	12JUN2014	
230855/2308550008	05JUN2014	Distant recurrence	Bone	Radiological	No	05JUN2014	
	27JUN2016	Death					
	09JAN2016	Central nervous system	Brain Metastasis	Radiological	No	09JAN2016	
230860/2308600006	22OCT2016	Distant recurrence	Liver	Radiological	No	22OCT2016	
230865/2308650011	28JUL2014	Distant recurrence	Lung	Radiological	Yes	28JUL2014	SCANT CARCINOMA CELLS SEEN
	29NOV2015	Death					
	23APR2015	Central nervous system	Brain Metastasis	Radiological	No	23APR2015	
230867/2308670006	27FEB2014	Local recurrence	Skin Or Soft Tissue Within The Local Area	Clinical	Yes	27FEB2014	INVASIVE DUCTAL CARCINOMA
	10MAR2014	Distant recurrence	Bone	Radiological	No	10MAR2014	
230868/2308680004	30SEP2015	Distant recurrence	Lung	Radiological	No	30SEP2015	
	25OCT2015	Death					
	30SEP2015	Distant recurrence	Pleural Effusion	Radiological	Yes	30SEP2015	METASTATIC ADENOCARCINOMA
230872/2308720009	22JUN2015	Distant recurrence	Lung	Radiological	No	22JUN2015	
230872/2308720010	02APR2016	Distant recurrence	Bone	Radiological	No	02APR2016	
	14MAY2016	Death					
	02APR2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	02APR2016	
	02APR2016	Distant recurrence	Lung	Radiological	No	02APR2016	
230873/2308730008	30DEC2015	Distant recurrence	Peritoneal Disease	Radiological	No	30DEC2015	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	03JUL2016	Death					
	14JAN2016	Distant recurrence	Bone	Radiological	No	14JAN2016	
	30DEC2015	Regional recurrence	Internal Mammary Lymph Nodes	Radiological	No	30DEC2015	
	30DEC2015	Local recurrence	Ipsilateral Anterior Chest Wall	Radiological	Yes	30DEC2015	DUCTAL CARCINOMA
	30DEC2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	30DEC2015	
230878/2308780026	20JUL2016	Distant recurrence	Bone	Radiological	No	20JUL2016	
230959/2309590005	22SEP2014	Distant recurrence	Lung	Radiological	Yes	22SEP2014	ADENOCARCINOMA
	25OCT2014	Central nervous system	Brain Metastasis	Radiological	No	25OCT2014	
	17OCT2014	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	17OCT2014	CARCINOMA
	08OCT2014	Distant recurrence	Bone	Radiological	No	08OCT2014	
230959/2309590022	01JUL2013	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	01JUL2013	L BREAST MULTIFOCAL BASAL CELL CARCINOMA
	07JUL2014	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	07JUL2014	BASAL CELL CARINCOMA OF LEFT BREAST
	21NOV2013	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	21NOV2013	BASAL CELL CARCINOMA OF NASAL AREA
230959/2309590026	25JUN2013	Non-invasive disease	Contralateral Lobular Carcinoma In Situ	Clinical	Yes	25JUN2013	FOCAL LOBULAR CARCINOMA IN SITU
231132/2311310001	20FEB2013	Distant recurrence	Bone	Radiological	No	20FEB2013	
	21FEB2014	Death					
	09JUL2013	Central nervous system	Brain Metastasis	Radiological	No	09JUL2013	
	21FEB2013	Distant recurrence	Lung	Radiological	No	21FEB2013	
231132/2311310004	09OCT2014	Local recurrence	Ipsilateral Breast	Radiological	Yes	09OCT2014	INFILTRATIVE DUCTAL CARCINOMA
231132/2311320005	13SEP2012	Central nervous system	Brain Metastasis	Radiological	No	13SEP2012	
231132/2311320011	30JUL2015	Local recurrence	Breast Surgical Scar	Clinical	Yes	30JUL2015	ADENOCARCINOMA DUCTAL
231143/2311430005	11JUL2016	Death					
231143/2311430006	29JAN2016	Distant recurrence	Bone	Radiological	No	29JAN2016	
	06FEB2016	Distant recurrence	Liver	Radiological	No	06FEB2016	
231193/2311930002	02JUL2014	Second primary malignancy	Lung Cancer	Radiological	Yes	02JUL2014	SQUAMOUS CELL CARCINOMA
	05NOV2014	Death					
231248/2312480014	21APR2016	Distant recurrence	Bone	Clinical	Yes	21APR2016	HER2 POS ER POS
231264/2312640004	21JUL2016	Second primary malignancy	Prostate Cancer	Radiological	Yes	21JUL2016	ADENOCARCINOMA
231270/2312700023	27JUN2014	Distant recurrence	Mediastinum	Radiological	Yes	27JUN2014	INVASIVE DUCTAL CARCINOMA RE-, RP-, HER-
	21APR2016	Death					
231270/2312700025	19NOV2015	Second primary malignancy	Melanoma (Axillary)	Clinical	Yes	19NOV2015	SSM TYPE, CLARK III
231271/2312710004	12NOV2014	Distant recurrence	Bone	Radiological	No	12NOV2014	
231271/2312710027	09AUG2013	Central nervous system	Brain Metastasis	Radiological	No	09AUG2013	
231285/2312850004	22APR2015	Death					
231285/2312850011	04AUG2014	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	04AUG2014	INVASIVE DUCTAL CARCINOMA GRADE III
231285/2312850023	11JUN2014	Local recurrence	Ipsilateral Breast	Radiological	Yes	11JUN2014	INVASIVE DUCTAL CARCINOMA
	26OCT2015	Death					

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	25JUL2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	25JUL2014	
	25JUL2014	Distant recurrence	Lung	Radiological	No	25JUL2014	
231287/2312870016	07SEP2015	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	07SEP2015	IN SITU DUCTAL CARCINOMA
231290/2312900010	12NOV2015	Distant recurrence	Liver	Radiological	Yes	12NOV2015	LIVER METASTASIS OF MAMMARY CARCINOMA
231294/2312940003	18MAR2016	Central nervous system	Brain Metastasis	Radiological	No	18MAR2016	
	02AUG2016	Death					
231296/2312960002	11JAN2016	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	11JAN2016	INVASIVE LOBULAR CARCINOMA
231299/2312990005	12JAN2015	Distant recurrence	Liver	Radiological	No	12JAN2015	
	21APR2016	Death					
	24JAN2015	Distant recurrence	Bone	Radiological	No	24JAN2015	
	12JAN2015	Regional recurrence	Supraclavicular Lymph Nodes	Radiological	No	12JAN2015	
	12JAN2015	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	No	12JAN2015	
	12JAN2015	Regional recurrence	Infraclavicular Lymph Nodes	Radiological	No	12JAN2015	
	12JAN2015	Local recurrence	Ipsilateral Anterior Chest Wall	Radiological	No	12JAN2015	
	12JAN2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	12JAN2015	
	12JAN2015	Distant recurrence	Lung	Radiological	No	12JAN2015	
231410/2314100006	09MAY2013	Local recurrence	Breast Surgical Scar	Radiological	Yes	09MAY2013	DUCTAL CARCINOMA
231418/2314180008	02MAY2013	Second primary malignancy	Acute Myeloid Leukemia	Clinical	Yes	02MAY2013	MYELOID LEUKEMIA
	06NOV2014	Death					
231418/2314180022	04NOV2013	Distant recurrence	Liver	Radiological	Yes	04NOV2013	LIVER TISSUE WITH PRIMARY BREAST CANCER METASTASIS
	24JUL2016	Death					
	08NOV2013	Central nervous system	Brain Metastasis	Radiological	No	08NOV2013	
	06NOV2013	Distant recurrence	Bone	Radiological	No	06NOV2013	
231418/2314180031	07MAR2015	Central nervous system	Brain Metastasis	Clinical	No	07MAR2015	
	09JUL2016	Death					
231449/2314490002	24MAR2016	Death					
231449/2314490009	27AUG2014	Distant recurrence	Liver	Clinical	Yes	27AUG2014	METASTASIS OF INVASIVE DUCTALES CARCINOM
	23MAR2016	Death					
231450/2314500004	20MAR2014	Local recurrence	Ipsilateral Breast	Radiological	Yes	20MAR2014	INVASIV
231450/2314500006	12AUG2014	Distant recurrence	Lung	Clinical	Yes	12AUG2014	METATSTASIS MAMMA CA
231454/2314540001	20AUG2014	Local recurrence	Skin Or Soft Tissue Within The Local Area	Radiological	Yes	20AUG2014	MALIGNANT
	14MAR2016	Central nervous system	Meningitis Carcinomatosa	Radiological	No	14MAR2016	
	11MAR2016	Central nervous system	Brain Metastasis	Radiological	No	11MAR2016	
231455/2314550008	30SEP2012	Death					
231455/2314550023	16OCT2015	Central nervous system	Brain Metastasis	Radiological	Yes	16OCT2015	SOLITARY BRAIN METASTASIS HER2 POSITIVE
231456/2314560001	03APR2014	Distant recurrence	Liver	Radiological	No	03APR2014	
	12OCT2015	Death					
	30JAN2015	Central nervous system	Brain Metastasis	Radiological	No	30JAN2015	
	03JUL2014	Distant recurrence	Pleural Effusion	Radiological	Yes	03JUL2014	MESOTHELCELLPROLIFERATION

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
231456/2314560016	25FEB2016	Distant recurrence	Bone	Radiological	No	25FEB2016	
231461/2314610003	22NOV2013	Central nervous system	Brain Metastasis	Radiological	Yes	22NOV2013	UNDIFFERENTIATED CARCINOMA
231463/2314630002	17JUN2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	17JUN2014	G3
	03AUG2014	Death					
231463/2314630004	21AUG2014	Second primary malignancy	Gastric Cancer	Clinical	Yes	21AUG2014	GIST
	27JAN2015	Death					
231482/2314820006	05JUL2016	Local recurrence	Skin Or Soft Tissue Within The Local Area	Clinical	Yes	05JUL2016	L1 OF SKIN FROM THE CHEST WALL
231616/2316160005	21JUL2015	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	21JUL2015	INVASIV BREASTCANCER GRADING 3, RPT1C, L0, V1, R0
231621/2316210011	29MAR2013	Distant recurrence	Bone	Radiological	Yes	29MAR2013	CARCINOMA METASTATICUM
	19JUN2013	Central nervous system	Brain Metastasis	Radiological	No	19JUN2013	
231621/2316210014	19JUN2012	Distant recurrence	Liver	Radiological	No	19JUN2012	
	05OCT2016	Death					
231621/2316210044	14JAN2014	Second primary malignancy	Carvinoma Papillare Of Thyroid Gland	Clinical	Yes	14JAN2014	MALIGNICITY
231628/2316280005	27JUL2015	Distant recurrence	Liver	Radiological	No	27JUL2015	
	27JUL2015	Distant recurrence	Lung	Radiological	Yes	27JUL2015	HER2 SISH POSITIVE
231630/2316300012	07JUN2016	Second primary malignancy	Peritoneal	Radiological	Yes	07JUN2016	PRIMITIVE PERITONEAL SEROUS CARCINOMA
231670/2316700009	28MAR2013	Distant recurrence	Liver	Radiological	No	28MAR2013	
231670/2316700014	05MAY2014	Central nervous system	Brain Metastasis	Radiological	No	05MAY2014	
	21APR2015	Death					
231672/2316720004	04JUL2012	Second primary malignancy	Melanoma	Clinical	Yes	04JUL2012	EPITHELOID
231762/2317620003	19DEC2014	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	19DEC2014	INVASIVE
	30JUN2015	Non-invasive disease	Lentigo Maligna	Clinical	Yes		CARCINOMA
231834/2318340004	25FEB2014	Distant recurrence	Lung	Radiological	Yes	25FEB2014	METASTASIS
231842/2318420003	09FEB2015	Distant recurrence	Liver	Radiological	Yes	09FEB2015	DUCTAL CARCINOMA
231901/2319010004	05NOV2013	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	05NOV2013	KERATINZING SQAMOUS CELL CARCINOMA
	05NOV2013	Non-invasive disease	Multricentric Superficial Basalioma	Clinical	Yes	05NOV2013	BASALIOMA
	05NOV2013	Non-invasive disease	Lentigo Maligna	Clinical	Yes	05NOV2013	LENTIGO MALIGNA
232050/2320500002	31AUG2012	Distant recurrence	Bone	Radiological	No	31AUG2012	
232093/2320930004	01DEC2014	Distant recurrence	Bone	Radiological	No	01DEC2014	
	05FEB2016	Death					
	01DEC2014	Distant recurrence	Lung	Radiological	No	01DEC2014	
232102/2321020006	26JUL2013	Distant recurrence	Liver	Radiological	No	26JUL2013	
232219/2322190013	21NOV2014	Distant recurrence	Pleural Effusion	Radiological	Yes	21NOV2014	EFFUSION METASTATIC
	17NOV2015	Death					
232219/2322190016	25NOV2015	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	25NOV2015	WELL DIFFERENTIAL CANCER-INVASIVE CARCINOMA
	25NOV2015	Distant recurrence	Bone	Radiological	No	25NOV2015	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
232273/232273001 7	03AUG2015	Distant recurrence	Bone	Radiological	No	03AUG2015	
	09DEC2016	Death					
	03AUG2015	Distant recurrence	Lung	Radiological	No	03AUG2015	
	03AUG2015	Distant recurrence	Liver	Radiological	No	03AUG2015	
232273/232273003 0	21FEB2015	Central nervous system	Brain Metastasis	Radiological	No	21FEB2015	
	01SEP2015	Death					
232279/232279000 3	04APR2016	Death					
232279/232279000 6	13AUG2016	Death					
232279/232279001 0	20APR2015	Contralateral breast cancer	Contralateral Breast Cancer	Clinical	Yes	20APR2015	INFILTRATIVE DUCTAL CARCINOMA
232300/232300002 0	26MAR2013	Local recurrence	Skin Or Soft Tissue Within The Local Area	Radiological	Yes	26MAR2013	ADENOCARCINOMA
	29JUL2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	29JUL2015	
232300/232300003 1	05MAR2015	Local recurrence	Breast Surgical Scar	Clinical	Yes	05MAR2015	INFILTRATIVE DUCTAL CARCINOMA
232300/233618000 2	08APR2015	Contralateral breast cancer	Contralateral Breast Cancer	Clinical	Yes	08APR2015	INFILTRATIVE DUCTAL CARCINOMA
	23JUL2015	Death					
232303/232303000 4	23APR2014	Distant recurrence	Lung	Radiological	No	23APR2014	
	22FEB2015	Death					
	23APR2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	23APR2014	
232303/232303001 8	21JAN2014	Central nervous system	Brain Metastasis	Radiological	No	21JAN2014	
	16APR2015	Death					
232324/232324002 9	15JAN2015	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	15JAN2015	IDC AND DCIS
232324/232324004 4	09DEC2014	Distant recurrence	Lung	Radiological	No	09DEC2014	
	08JUN2016	Death					
	26MAR2016	Central nervous system	Brain Metastasis	Radiological	No	26MAR2016	
232334/232334000 7	06JAN2015	Distant recurrence	Liver	Radiological	Yes	06JAN2015	ADENOCARCINOMA
232335/232335001 8	09JUN2014	Non-invasive disease	Ipsilateral Ductal Carcinoma In Situ	Radiological	Yes	09JUN2014	PTIS/G3
232343/232343001 4	11JUN2014	Central nervous system	Brain Metastasis	Radiological	No	11JUN2014	
	04SEP2014	Death					
232451/232451000 1	18DEC2016	Death					
232462/232462000 3	01SEP2016	Distant recurrence	Liver	Radiological	Yes	01SEP2016	METASTASIS ADENOCARCINOMA
	27SEP2016	Distant recurrence	Bone	Radiological	No	27SEP2016	
232474/232474000 1	07MAR2014	Distant recurrence	Liver	Radiological	No	07MAR2014	
	23MAR2014	Death					
232489/232489000 3	02AUG2013	Central nervous system	Brain Metastasis	Radiological	No	02AUG2013	
232542/209059000 3	04JUL2013	Distant recurrence	Lung	Radiological	No	04JUL2013	
	12OCT2015	Death					
	12MAR2014	Central nervous system	Brain Metastasis	Radiological	No	12MAR2014	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	24SEP2013	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	24SEP2013	
232557/2325570014	14MAR2016	Local recurrence	Ipsilateral Breast	Radiological	Yes	14MAR2016	CT1B (8MM)CN0ER2PR2HER 2 NEU 3+
232561/2325610001	07OCT2013	Central nervous system	Brain Metastasis	Radiological	No	07OCT2013	
	12DEC2014	Death					
232584/2325840002	18APR2013	Death					
232615/2326150005	18DEC2015	Distant recurrence	Bone	Radiological	No	18DEC2015	
232618/2326180014	19DEC2013	Regional recurrence	Skin Or Soft Tissue Within The Regional Area	Clinical	Yes	19DEC2013	CARCINOMA DUCTAL
	21NOV2014	Death					
	22JAN2014	Distant recurrence	Lung	Radiological	No	22JAN2014	
	22JAN2014	Distant recurrence	Liver	Radiological	No	22JAN2014	
232618/2326180017	04SEP2015	Second primary malignancy	Leukemya Secondary To Oncology Chemotherapy	Clinical	Yes	04SEP2015	TYPE B LYMPHOBLASTIC
232618/2326180018	21FEB2014	Local recurrence	Breast Surgical Scar	Clinical	Yes	21FEB2014	DUCTAL BREAST CANCER
	18FEB2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	18FEB2015	
	18FEB2015	Distant recurrence	Lung	Radiological	No	18FEB2015	
	18FEB2015	Distant recurrence	Bone	Radiological	No	18FEB2015	
	15OCT2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Clinical	Yes	15OCT2014	DUCTAL BREAST CANCER
232618/2326180020	14MAY2015	Central nervous system	Brain Metastasis	Radiological	No	14MAY2015	
232634/2326340003	18SEP2014	Non-invasive disease	Ipsilateral Ductal Carcinoma In Situ	Radiological	Yes	18SEP2014	DCSI
	02FEB2015	Distant recurrence	Lung	Radiological	Yes	02FEB2015	BREAST CARCINOMA
232634/2326340004	03APR2014	Local recurrence	Ipsilateral Breast	Radiological	Yes	03APR2014	DUCTAL CARCINOMA
	22JUN2016	Distant recurrence	Lung	Radiological	Yes	22JUN2016	MTS BREAST CANCER RH NEG HER 2: +++
	18MAR2015	Distant recurrence	Bone	Radiological	No	18MAR2015	
	23FEB2015	Distant recurrence	Liver	Radiological	No	23FEB2015	
	03APR2014	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	03APR2014	DUCTAL CARCINOMA
232634/2326340011	10APR2014	Distant recurrence	Bone	Radiological	No	10APR2014	
	10APR2014	Distant recurrence	Soft Tissue Mass	Radiological	No	10APR2014	
232667/2326670005	04JAN2016	Central nervous system	Brain Metastasis	Radiological	No	04JAN2016	
232668/2326680008	24JUL2014	Central nervous system	Brain Metastasis	Radiological	No	24JUL2014	
	21OCT2014	Death					
232676/2326760016	12JUN2014	Central nervous system	Brain Metastasis	Radiological	No	12JUN2014	
	22FEB2016	Death					
232677/2326770006	29DEC2014	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	29DEC2014	DUCTAL INFILTRANT CARCINOMA
232677/2326770008	24JAN2013	Distant recurrence	Liver	Radiological	No	24JAN2013	
	14APR2014	Death					
	17JAN2014	Local recurrence	Breast Surgical Scar	Radiological	No	17JAN2014	
	24JAN2013	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	24JAN2013	
	24JAN2013	Distant recurrence	Lung	Radiological	No	24JAN2013	
232678/2326780009	24JAN2014	Second primary malignancy	Gastric Cancer	Radiological	Yes	24JAN2014	GASTRIC CANCER

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	12JUL2014	Death					
232678/2326780010	27FEB2014	Central nervous system	Brain Metastasis	Radiological	No	27FEB2014	
	30JAN2015	Death					
233101/2331010004	19JUN2015	Second primary malignancy	Melanoma-Right Lower Abdomen	Clinical	Yes	19JUN2015	CARCINOMA
233103/2331030003	27APR2012	Distant recurrence	Lung	Radiological	No	27APR2012	
233135/2331350008	14SEP2016	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	14SEP2016	BASALIOMA
233195/2331950001	05MAY2014	Distant recurrence	Bone	Radiological	Yes	05MAY2014	METASTATIC CA, BREAST ORIGIN
233285/2332850002	06JUN2012	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	06JUN2012	INVASIVE DUCTAL CARCINOMA, GRADE 3
	21MAR2013	Death					
	19DEC2012	Distant recurrence	Lung	Radiological	No	19DEC2012	
233285/2332850009	26MAR2014	Central nervous system	Brain Metastasis	Radiological	No	26MAR2014	
	04DEC2014	Death					
233285/2332850012	01OCT2015	Second primary malignancy	Leiomyosarcoma Of Small Intestine	Radiological	Yes	01OCT2015	LIPOSARCOMA
233285/2332850017	08JUL2016	Distant recurrence	Liver	Radiological	No	08JUL2016	
233617/2336170004	24SEP2014	Central nervous system	Brain Metastasis	Radiological	No	24SEP2014	
	10APR2015	Death					
	25MAR2015	Distant recurrence	Liver	Radiological	No	25MAR2015	
233617/2336170006	04JAN2015	Regional recurrence	Skin Or Soft Tissue Within The Regional Area	Clinical	No	04JAN2015	
	28DEC2015	Death					
234261/2342610004	18DEC2015	Central nervous system	Brain Metastasis	Radiological	No	18DEC2015	
	20JUN2016	Death					
234306/2343060001	23JUL2015	Distant recurrence	Bone	Radiological	No	23JUL2015	
	10SEP2015	Death					
	23JUL2015	Distant recurrence	Liver	Radiological	No	23JUL2015	
234308/2343080004	03JUN2012	Death					
234310/2343100001	27JUN2014	Central nervous system	Brain Metastasis	Radiological	No	27JUN2014	
	01AUG2014	Distant recurrence	Bone	Radiological	No	01AUG2014	
234310/2343100011	31DEC2015	Local recurrence	Ipsilateral Breast	Radiological	Yes	31DEC2015	MIXED DCIS + INVASIVE DUCTAL
234310/2343100015	19FEB2015	Distant recurrence	Lung	Radiological	No	19FEB2015	
234310/2343100031	05AUG2014	Distant recurrence	Liver	Radiological	No	05AUG2014	
234314/2343140009	29JUN2016	Distant recurrence	Bone	Radiological	No	29JUN2016	
234342/2343420005	19NOV2014	Death					
234618/2346180014	15DEC2015	Local recurrence	Ipsilateral Breast	Radiological	Yes	15DEC2015	INVASIVE DUCTAL CARCINOMA
	09NOV2016	Second primary malignancy	Colon Adenocarcinoma	Radiological	Yes	09NOV2016	METASTATIC CARCINOMA
234739/2347390011	26AUG2015	Distant recurrence	Bone	Radiological	Yes	26AUG2015	INVASIVE DUCTAL CA

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
235068/2350680003	18APR2013	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Clinical	Yes	18APR2013	ADENOCARCINOMA C/W METS FROM PRIMARY BREAST
235072/2350720012	12NOV2015	Distant recurrence	Lung	Radiological	Yes	12NOV2015	METASTATIC MAMMARY CARCINOMA
	12NOV2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	12NOV2015	METASTATIC MAMMARY CARCINOMA
237287/2372870012	25JUN2014	Distant recurrence	Pericardium	Radiological	Yes	25JUN2014	NON-SMALL CELL CARCINOMA, CONSITENT WITH A METASTA
	17NOV2014	Death					
237290/2342410003	15JUL2014	Regional recurrence	Skin Or Soft Tissue Within The Regional Area	Clinical	Yes	15JUL2014	INFILTRATING DUCTAL MAMMARY CARCINOMA
	23JUL2014	Distant recurrence	Bone	Radiological	No	23JUL2014	
237290/2372900029	04SEP2015	Distant recurrence	Bone	Radiological	No	04SEP2015	
	04SEP2015	Distant recurrence	Liver	Radiological	Yes	04SEP2015	ADENOCARCINOMA
237995/2379950002	11NOV2013	Distant recurrence	Lung	Radiological	No	11NOV2013	
	15MAY2015	Death					
	13NOV2013	Central nervous system	Brain Metastasis	Radiological	No	13NOV2013	
	11NOV2013	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	Yes	11NOV2013	METASTATIC CARCINOMA
237995/2379950013	23MAY2013	Non-invasive disease	Contralateral Lobular Carcinoma In Situ	Radiological	Yes	23MAY2013	LCIS
238744/2387440003	09NOV2016	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	Yes	09NOV2016	INVASIVE DUCTAL CARCINOMA
	25NOV2016	Distant recurrence	Bone	Radiological	No	25NOV2016	
238744/2387440007	31MAR2016	Central nervous system	Brain Metastasis	Radiological	No	31MAR2016	
238744/2387440009	04JUL2016	Distant recurrence	Bone	Radiological	No	04JUL2016	
243805/2438050003	02DEC2014	Second primary malignancy	Sigmoid Colon Cancer	Radiological	Yes	02DEC2014	WELL-DIFFERENTIATED ADENOCARCINOMA
243807/2438070017	09JUL2014	Second primary malignancy	Small Cell Lung Cancer	Radiological	Yes	09JUL2014	SMALL CELL CARCINOMA
	27DEC2015	Death					
243808/2438080002	22MAY2015	Distant recurrence	Liver	Radiological	Yes	22MAY2015	METASTATIC CARCINOMA
	22MAY2015	Distant recurrence	Lung	Radiological	No	22MAY2015	
243808/2438080019	02MAY2016	Death					
243821/2438210010	18OCT2016	Non-invasive disease	Bowen's Disease	Clinical	Yes	18OCT2016	SQUAMOUS
243834/2438340032	29APR2015	Central nervous system	Brain Metastasis	Radiological	No	29APR2015	
	19MAY2015	Death					
	14MAY2015	Distant recurrence	Pancreas	Radiological	No	14MAY2015	
	14MAY2015	Distant recurrence	Liver	Radiological	No	14MAY2015	
	01MAY2015	Regional recurrence	Ipsilateral Axillary Lymph Nodes	Radiological	No	01MAY2015	
	01MAY2015	Distant recurrence	Lung	Radiological	No	01MAY2015	
	01MAY2015	Distant recurrence	Bone	Radiological	No	01MAY2015	
243837/2438370011	30JUN2015	Distant recurrence	Lung	Radiological	No	30JUN2015	
	23JUL2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	23JUL2015	
243839/2438390015	10JUL2015	Distant recurrence	Bone	Radiological	No	10JUL2015	
243842/2438420007	23SEP2016	Distant recurrence	Bone	Radiological	No	23SEP2016	

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
243970/2439700005	04JUL2013	Central nervous system	Brain Metastasis	Radiological	Yes	04JUL2013	METASTATIC CARCINOMA
243973/2439730003	07AUG2013	Non-invasive disease	Basal Or Squamous Cell Carcinoma Of The Skin	Clinical	Yes	07AUG2013	NODULAR BASAL CELL CARCINOMA
244708/2447080004	26JUN2016	Central nervous system	Brain Metastasis	Radiological	No	26JUN2016	
246904/2469040005	01MAR2016	Second primary malignancy	Acute Myeloid Leukemia	Clinical	Yes	01MAR2016	ACUTE MYELOID LEUKEMIA
246912/2469120005	30APR2013	Death					
246977/2469770002	25FEB2014	Distant recurrence	Liver	Radiological	No	25FEB2014	
	11MAR2015	Death					
	05MAR2014	Distant recurrence	Bone	Radiological	No	05MAR2014	
246978/2469780009	21NOV2013	Non-invasive disease	Myelodysplastic Syndrome	Clinical	No	21NOV2013	
250537/2505370009	23JUN2015	Regional recurrence	Supraclavicular Lymph Nodes	Clinical	Yes	23JUN2015	ADENOCARCINOMA OF LYMPH NODE METASTASIS
250537/2505370010	01SEP2016	Contralateral breast cancer	Contralateral Breast Cancer	Clinical	Yes	01SEP2016	INVASIVE CARCINOMA
250537/2505370011	09SEP2015	Non-invasive disease	Contralateral Ductal Carcinoma In Situ	Radiological	Yes	09SEP2015	DCIS
	11AUG2016	Distant recurrence	Bone	Clinical	Yes	11AUG2016	METASTATIC CANCER
250540/2505400005	11OCT2013	Distant recurrence	Lung	Radiological	No	11OCT2013	
	05SEP2015	Death					
250841/2508410017	20FEB2013	Local recurrence	Ipsilateral Anterior Chest Wall	Clinical	Yes	20FEB2013	ADENOCARCINOMA CELL
250841/2508410043	18FEB2014	Distant recurrence	Liver	Radiological	No	18FEB2014	
	11APR2015	Death					
250841/2508410053	24APR2014	Distant recurrence	Bone	Radiological	No	24APR2014	
	14SEP2015	Death					
	15MAR2015	Distant recurrence	Liver	Radiological	No	15MAR2015	
250841/2508410070	26OCT2014	Distant recurrence	Bone	Radiological	No	26OCT2014	
	31OCT2014	Distant recurrence	Liver	Radiological	No	31OCT2014	
250841/2508410071	18APR2016	Contralateral breast cancer	Contralateral Breast Cancer	Radiological	Yes	18APR2016	INFILTRATIVE CARCINOMA
250841/2508410077	26MAY2014	Death					
250841/2508410101	10JUL2014	Distant recurrence	Bone	Radiological	No	10JUL2014	
	21FEB2015	Death					
250842/2508420007	17NOV2014	Distant recurrence	Bone	Radiological	Yes	17NOV2014	POORLY DIFFERENTIATED CARCINOMA, INVOLVING THE BON
250846/2508460011	10JUN2015	Central nervous system	Brain Metastasis	Radiological	No	10JUN2015	
	26JUL2015	Death					
	10JUN2015	Distant recurrence	Lung	Radiological	No	10JUN2015	
	10JUN2015	Distant recurrence	Liver	Radiological	No	10JUN2015	
	10JUN2015	Distant recurrence	Bone	Radiological	No	10JUN2015	
250846/2508460016	23JAN2015	Distant recurrence	Liver	Radiological	Yes	23JAN2015	LIVER NODE(POOR IN DIFFERENTIATION CANCER)
	23JAN2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	23JAN2015	
250846/2508460025	19NOV2014	Local recurrence	Ipsilateral Anterior Chest Wall	Radiological	Yes	19NOV2014	INVASIVE CANCER OF SKIN ULCER TISSUE

Centre/patient ID	Date of recurrence	Category of recurrence	Site of recurrence	Method of evaluation	Biopsy	Biopsy date	Histology type
	10FEB2016	Death					
	27NOV2014	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	27NOV2014	
	27NOV2014	Distant recurrence	Lung	Radiological	No	27NOV2014	
250847/2508470003	14JUL2015	Regional recurrence	Supraclavicular Lymph Nodes	Clinical	Yes	14JUL2015	METASTATIC ADENOCARCINOMA
	23SEP2016	Death					
	20JUL2015	Distant recurrence	Lung	Radiological	No	20JUL2015	
	20JUL2015	Central nervous system	Brain Metastasis	Radiological	No	20JUL2015	
	17JUL2015	Distant recurrence	Bone	Radiological	No	17JUL2015	
	16JUL2015	Distant recurrence	Liver	Radiological	No	16JUL2015	
250848/2508480027	10APR2015	Second primary malignancy	Lung Cancer	Radiological	No	10APR2015	
250849/2508490031	05JUN2014	Central nervous system	Brain Metastasis	Radiological	No	05JUN2014	
250849/2508490039	07JUN2015	Death					
250850/2508500013	08JAN2015	Distant recurrence	Lung	Radiological	No	08JAN2015	
	04MAR2016	Death					
	08JAN2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	08JAN2015	
250850/2508500021	27JAN2015	Distant recurrence	Lung	Radiological	No	27JAN2015	
	27JAN2015	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	27JAN2015	
250851/2508510005	23MAR2015	Distant recurrence	Bone	Radiological	No	23MAR2015	
250851/2508510018	22SEP2016	Distant recurrence	Lung	Radiological	No	22SEP2016	
	22SEP2016	Distant recurrence	Skin Or Lymph Nodes Other Than Specified On Local/Regional Recurrence Page	Radiological	No	22SEP2016	
251800/2518000025	15JUN2016	Second primary malignancy	Sarcoma	Clinical	Yes		POORLY DIFFERENTED CANCER
	19JUL2016	Distant recurrence	Lung	Radiological	No	19JUL2016	
278617/2438460004	09SEP2015	Distant recurrence	Bone	Radiological	No	09SEP2015	
278617/2438460019	24AUG2016	Local recurrence	Ipsilateral Breast	Radiological	Yes	24AUG2016	DUCTAL

Clinical cut-off: 19DEC2016

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_rec.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CSRPrimary/prod/output/oth_rec_26a_19DEC2016_CHNS.xls
30MAR2020 15:29

Sonstige Analysen (Datenschnitt: 19.12.2016)

Stratifizierungsfaktoren

POPULATION: HR Negative or Node Positive, ITT
ENDPOINT: All patients
STUDY: j25126a
Randomization Stratification Factors by Treatment Regimen
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK
THIS LINE LEFT BLANK

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)
Nodal status		
n	1811	1823
0 positive nodes and tumor <= 1cm*	51 (2.8%)	43 (2.4%)
0 positive nodes and tumor > 1cm*	257 (14.2%)	278 (15.2%)
1-3 positive nodes	907 (50.1%)	900 (49.4%)
>= 4 positive nodes	596 (32.9%)	602 (33.0%)
Adjuvant chemotherapy regimen (randomized)		
n	1811	1823
Anthracycline containing regimen	1439 (79.5%)	1448 (79.4%)
Non-anthracycline containing regimen	372 (20.5%)	375 (20.6%)
Hormone receptor status (central)		
n	1811	1823
Negative (ER and PgR negative)	864 (47.7%)	858 (47.1%)
Positive (ER and/or PgR positive)	947 (52.3%)	965 (52.9%)
Geographical Region		
n	1811	1823
USA	221 (12.2%)	226 (12.4%)
Canada/Western Europe/Australia-New Zealand/South Africa	938 (51.8%)	936 (51.3%)
Eastern Europe	160 (8.8%)	162 (8.9%)
Asia Pacific	446 (24.6%)	450 (24.7%)
Latin America	46 (2.5%)	49 (2.7%)
Protocol Version		
n	1811	1823
Protocol A	1240 (68.5%)	1246 (68.3%)
Protocol Amendment B	571 (31.5%)	577 (31.7%)

* Protocol A only
Clinical cut-off: 19Dec2016

Program: /opt/BIOSTAT/prod/cdp11450.pbe/r25126a.pbe/t_dm_strata.sas
Output: /opt/BIOSTAT/prod/cd11450g.pbe/j25126a.pbe/reports/t_dm_strata_26a_TRT1P_IT_CHON.xls
11OCT2017 8:33

Sonstige Analysen (Datenschnitt: 19.06.2019)

Todesfälle

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Number of patients who died including primary reason

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
All deaths	108 (6.0%)	130 (7.1%)	238 (6.5%)
Primary reason			
Recurrence of disease	76 (4.2%)	98 (5.4%)	174 (4.8%)
Adverse event	19 (1.0%)	20 (1.1%)	39 (1.1%)
Other	13 (0.7%)	12 (0.7%)	25 (0.7%)

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_dth.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_dth_26c_19JUN2019_CHON.xls
30MAR2020 16:25

Sonstige Analysen (Datenschnitt: 19.06.2019)

Unerwünschte Ereignisse die zum Tode führen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of AEs leading to death

Treatment: PERTUZUMAB (N=1783)

Centre/patient ID	Age/sex/race	study drug administration	Study day of first Pertuzumab/placebo	study drug administration	Day of onset	Day of death	AE preferred term
[redacted]	[redacted]	30JAN2013	64	64	68	68	ROAD TRAFFIC ACCIDENT
[redacted]	[redacted]	20MAR2012	1	59	64	65	FEBRILE NEUTROPENIA
[redacted]	[redacted]	27JUN2013	85	154	173	174	HYPERKALAEMIA
[redacted]	[redacted]	22JAN2013	92	134	154	160	PNEUMONIA ASPIRATION
[redacted]	[redacted]	04FEB2013	93	457	492	760	GASTROINTESTINAL CARCINOMA
[redacted]	[redacted]	15NOV2012	1	260	274	275	CEREBRAL HAEMORRHAGE
			1	260	274	275	SUBARACHNOID HAEMORRHAGE
[redacted]	[redacted]	30OCT2012	65	338	297	554	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	10JUL2013	1	353	1029	1242	METASTATIC MALIGNANT MELANOMA
[redacted]	[redacted]	22NOV2012	1	133	146	175	INTERSTITIAL LUNG DISEASE
[redacted]	[redacted]	17JUN2013	64	337	1107	1261	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	25APR2013	85	121	453	453	CARDIOGENIC SHOCK
[redacted]	[redacted]	02JUL2012	71	135	1334	1334	MITRAL VALVE DISEASE
[redacted]	[redacted]	07NOV2012	99	148	161	175	SEPSIS
[redacted]	[redacted]	17MAY2012	1	22	1087	1144	GLIOBLASTOMA
[redacted]	[redacted]	29AUG2012	97	225	288	542	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	14NOV2012	113	260	685	1078	TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED
[redacted]	[redacted]	05FEB2013	86	443	446	738	ACUTE MYELOID LEUKAEMIA

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_aefatal.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_aefatal_26c_19JUN2019_CHNS.xls
30MAR2020 16:39

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of AEs leading to death

Treatment: PLACEBO (N=1822)

Centre/patient ID	Age/sex/race	study drug administration	Study day of first Pertuzumab/placebo	study drug administration	Day of onset	Day of death	AE preferred term
[redacted]	[redacted]	25FEB2013	65	421	1052	1231	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	29MAR2013	85	442	1824	2232	PANCREATIC CARCINOMA METASTATIC
[redacted]	[redacted]	20JUN2013		71	80	93	SEPSIS
[redacted]	[redacted]	29OCT2012	89	109	127	129	LUNG INFECTION
[redacted]	[redacted]	15APR2013	93	233	184	244	PULMONARY FIBROSIS
[redacted]	[redacted]	12JUN2012	1	1	7	8	INTESTINAL ISCHAEMIA
[redacted]	[redacted]	11SEP2012	1	218	220	582	ADENOCARCINOMA PANCREAS
[redacted]	[redacted]	27FEB2012	72	431	857	983	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	13JUL2012	1	358	1440	2070	PANCREATIC CARCINOMA
[redacted]	[redacted]	07JAN2013	64	424	1576	2083	MYELODYSPLASTIC SYNDROME
[redacted]	[redacted]	09JUL2012	92	276	298	851	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	21JUN2012	85	442		1373	CARDIAC FAILURE
[redacted]	[redacted]	01AUG2012		1	9	61	GASTROINTESTINAL PERFORATION
[redacted]	[redacted]	03OCT2012	71	435	1344	1529	MALIGNANT PERITONEAL NEOPLASM
[redacted]	[redacted]	27DEC2012	84	336	1684	1684	ACUTE MYOCARDIAL INFARCTION
[redacted]	[redacted]	27JUN2012	86	442	1636	1636	ACUTE MYOCARDIAL INFARCTION
[redacted]	[redacted]	18DEC2012	85	402	403	572	GASTRIC NEOPLASM
[redacted]	[redacted]	11MAY2012		1	18	24	SEPTIC SHOCK
[redacted]	[redacted]	05JUL2013	88	389	370	906	SMALL CELL LUNG CANCER
[redacted]	[redacted]	07MAR2013	1	358	1091	1928	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	20MAR2013	1	1	8	42	COLITIS
[redacted]	[redacted]	29MAR2013	89	447		2203	SARCOMA

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_aefatal.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_aefatal_26c_19JUN2019_CHNS.xls
30MAR2020 16:39

Sonstige Analysen (Datenschnitt: 19.06.2019)

Unerwünschtes Ereignis: Diarrhö

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Diarrhoea
MODEL: --
STUDY: BO25126
Exploration of Diarrhoea Adverse Events by Treatment Regimen

	Pertuzumab + Trastuzumab + Chemotherapy (N=1783)	Placebo + Trastuzumab + Chemotherapy (N=1822)
Total patients reporting at least 1 event	1257	824
Number of events per patient		
n	1257	824
Mean (SD)	2.04 (1.96)	1.66 (1.35)
Median	1	1
Min - Max	1.0 - 26.0	1.0 - 18.0
Total number of events	2568 (100%)	1371 (100%)
Resolved	2537 (98.8%)	1352 (98.6%)
Unresolved	31 (1.2%)	19 (1.4%)
NCI CTCAE Grade (all events)		
n	2566 (100%)	1369 (100%)
Grade 1	1703 (66.4%)	983 (71.8%)
Grade 2	677 (26.4%)	311 (22.7%)
Grade 3	183 (7.1%)	75 (5.5%)
Grade 4	3 (0.1%)	0
Period of onset (all events)		
n	2565 (100%)	1368 (100%)
Anthracycline period	261 (10.2%)	265 (19.4%)
Targeted treatment and chemo period	1744 (68.0%)	868 (63.5%)
Targeted treatment post chemotherapy	560 (21.8%)	235 (17.2%)
Targeted treatment cycle at onset^		
n	2046 (100%)	994 (100%)
Cycle 1	754 (36.9%)	381 (38.3%)
Cycle 2	330 (16.1%)	167 (16.8%)
Cycle 3	211 (10.3%)	110 (11.1%)
Cycle 4	151 (7.4%)	65 (6.5%)
Cycle 5	77 (3.8%)	45 (4.5%)
Cycle 6	64 (3.1%)	40 (4.0%)
Cycle 7	57 (2.8%)	24 (2.4%)
Cycle 8	57 (2.8%)	19 (1.9%)

	Pertuzumab + Trastuzumab + Chemotherapy (N=1783)	Placebo + Trastuzumab + Chemotherapy (N=1822)
Cycle 9	47 (2.3%)	12 (1.2%)
Cycle 10	43 (2.1%)	16 (1.6%)
Cycle 11	52 (2.5%)	26 (2.6%)
Cycle 12	42 (2.1%)	21 (2.1%)
Cycle 13	39 (1.9%)	15 (1.5%)
Cycle 14	27 (1.3%)	12 (1.2%)
Cycle 15	27 (1.3%)	14 (1.4%)
Cycle 16	33 (1.6%)	11 (1.1%)
Cycle 17	19 (0.9%)	10 (1.0%)
Cycle 18	16 (0.8%)	5 (0.5%)
Cycle 20	0	1 (0.1%)
Time to onset of 1st event (days)		
n	1257	824
Mean (SD)	70.40 (59.18)	72.29 (75.39)
Median	71	66
Min - Max	0.0 - 426.0	1.0 - 474.0
Time from 1st targeted treatment to onset (days)*		
n	1160	700
Mean (SD)	25.41 (48.47)	42.32 (70.33)
Median	8	10
Min - Max	1.0 - 354.0	1.0 - 384.0
Duration of longest event (days)		
n	1239	812
Mean (SD)	95.43 (137.96)	58.39 (111.38)
Median	34	13
Min - Max	1.0 - 811.0	1.0 - 1022.0
Duration of each event (days)		
n	2537	1351
Mean (SD)	51.53 (106.30)	38.12 (90.37)
Median	8	6
Min - Max	1.0 - 811.0	1.0 - 1022.0

Includes all AEs reported from the date of 1st dose of study medication up to 28 days after the last dose of study medication.
Diarrhoea events selected from the PT = 'DIARRHOEA', 'DIARRHOEA INFECTIOUS', 'DIARRHOEA HAEMORRHAGIC', 'DIARRHOEA NEONATAL', or 'POST PROCEDURAL DIARRHOEA'.
^ n = number of events started during the targeted treatment period.
* based on events started during the targeted treatment period.
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ae_diar.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_ae_diar_26c_19JUN2019_CHNS.xls
05AUG2020 16:59

Sonstige Analysen (Datenschnitt: 19.06.2019)

Verteilung der Patienten pro Arm

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Disposition of patients per arm

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
Randomized to study treatment	1811 (100%)	1823 (100%)	3634 (100%)
Received at least one dose of study drug	1794 (99.1%)	1811 (99.3%)	3605 (99.2%)
Completed Pertuzumab/placebo treatment	1533 (84.6%)	1582 (86.8%)	3115 (85.7%)
Discontinued Pertuzumab/placebo treatment	278 (15.4%)	241 (13.2%)	519 (14.3%)
Reason for Pertuzumab/placebo treatment discontinuation			
Adverse event	130 (7.2%)	118 (6.5%)	248 (6.8%)
Death	8 (0.4%)	4 (0.2%)	12 (0.3%)
Pregnancy	1 (<0.1%)	0	1 (<0.1%)
Lost to follow-up	0	1 (<0.1%)	1 (<0.1%)
Non-compliance with study drug	33 (1.8%)	23 (1.3%)	56 (1.5%)
Physician decision	20 (1.1%)	12 (0.7%)	32 (0.9%)
Protocol violation	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Recurrence of disease	20 (1.1%)	28 (1.5%)	48 (1.3%)
Contralateral breast cancer	2 (0.1%)	0	2 (<0.1%)
Withdrawal by subject	38 (2.1%)	35 (1.9%)	73 (2.0%)
Other	25 (1.4%)	17 (0.9%)	42 (1.2%)
Entered follow-up period	1788 (98.7%)	1805 (99.0%)	3593 (98.9%)
Completed follow-up period	0	0	0
Discontinued follow-up period	381 (21.0%)	452 (24.8%)	833 (22.9%)
Reason for discontinuation of follow-up period			
Adverse event	14 (0.8%)	15 (0.8%)	29 (0.8%)
Death	19 (1.0%)	18 (1.0%)	37 (1.0%)
Lost to follow-up	29 (1.6%)	32 (1.8%)	61 (1.7%)
Physician decision	5 (0.3%)	7 (0.4%)	12 (0.3%)
Recurrence of disease	147 (8.1%)	210 (11.5%)	357 (9.8%)
Contralateral breast cancer	9 (0.5%)	14 (0.8%)	23 (0.6%)
Withdrawal by subject	143 (7.9%)	143 (7.8%)	286 (7.9%)
Other	15 (0.8%)	13 (0.7%)	28 (0.8%)

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ds.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_ds_26c_19JUN2019_CHON.xls
05AUG2020 16:51

POPULATION: Intent-to-Treat Population
ENDPOINT: --
MODEL: --
STUDY: BO25126
Disposition of patients per arm

	PERTUZUMAB (N=2400) n (%)	PLACEBO (N=2404) n (%)	TOTAL (N=4804) n (%)
Randomized to study treatment	2400 (100%)	2404 (100%)	4804 (100%)
Received at least one dose of study drug	2378 (99.1%)	2391 (99.5%)	4769 (99.3%)
Completed Pertuzumab/placebo treatment	2028 (84.5%)	2100 (87.4%)	4128 (85.9%)
Discontinued Pertuzumab/placebo treatment	372 (15.5%)	304 (12.6%)	676 (14.1%)
Reason for Pertuzumab/placebo treatment discontinuation			
Adverse event	176 (7.3%)	149 (6.2%)	325 (6.8%)
Death	9 (0.4%)	6 (0.2%)	15 (0.3%)
Pregnancy	1 (<0.1%)	0	1 (<0.1%)
Lost to follow-up	0	1 (<0.1%)	1 (<0.1%)
Non-compliance with study drug	44 (1.8%)	29 (1.2%)	73 (1.5%)
Physician decision	30 (1.3%)	15 (0.6%)	45 (0.9%)
Protocol violation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Recurrence of disease	20 (0.8%)	29 (1.2%)	49 (1.0%)
Contralateral breast cancer	2 (<0.1%)	0	2 (<0.1%)
Withdrawal by subject	55 (2.3%)	47 (2.0%)	102 (2.1%)
Other	34 (1.4%)	25 (1.0%)	59 (1.2%)
Entered follow-up period	2369 (98.7%)	2381 (99.0%)	4750 (98.9%)
Completed follow-up period	0	0	0
Discontinued follow-up period	493 (20.5%)	549 (22.8%)	1042 (21.7%)
Reason for discontinuation of follow-up period			
Adverse event	20 (0.8%)	23 (1.0%)	43 (0.9%)
Death	24 (1.0%)	23 (1.0%)	47 (1.0%)
Lost to follow-up	41 (1.7%)	44 (1.8%)	85 (1.8%)
Physician decision	11 (0.5%)	10 (0.4%)	21 (0.4%)
Recurrence of disease	165 (6.9%)	231 (9.6%)	396 (8.2%)
Contralateral breast cancer	13 (0.5%)	15 (0.6%)	28 (0.6%)
Withdrawal by subject	203 (8.5%)	187 (7.8%)	390 (8.1%)
Other	16 (0.7%)	16 (0.7%)	32 (0.7%)

Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ds.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_ds_26c_19JUN2019_IT.xls
05AUG2020 16:47

Sonstige Analysen (Datenschnitt: 19.06.2019)

Follow-up time (UE, SUE, OS)

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Median follow-up duration (safety 1)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1783) n (%)	PLACEBO (N=1822) n (%)	TOTAL (N=3605) n (%)
n	1783	1822	3605
Median	14,92	14,95	14,95
Min - Max	0.1 - 18.5	0.0 - 85.8	0.0 - 85.8

Follow-up time is calculated as median[(min(data cut date, death date, last date alive, last dose of study treatment + 28 days, initiation of subsequent anti-cancer therapy)- randomization date + 1) / 30.4375].
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_fu_26c_19JUN2019_CHNS_SAF1DUR.xls
30MAR2020 16:31

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Median follow-up duration (safety 2)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1783) n (%)	PLACEBO (N=1822) n (%)	TOTAL (N=3605) n (%)
n	1783	1822	3605
Median	73,63	73,08	73,4
Min - Max	0.1 - 89.0	0.0 - 87.9	0.0 - 89.0

Follow-up time is calculated as median[(min(data cut date, death date, last date alive,
initiation of subsequent anti-cancer therapy)- randomization date + 1) / 30.4375].
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_fu_26c_19JUN2019_CHNS_SAF2DUR.xls
30MAR2020 16:32

POPULATION: HR negative or node positive ITT
ENDPOINT: Median follow-up duration (efficacy)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
n	1811	1823	3634
Median	73,56	73,23	73,41
Min - Max	0.0 - 89.0	0.0 - 88.5	0.0 - 89.0

Follow-up time is calculated as median[(min(data cut date, death date, last date alive)- randomization date + 1) / 30.4375].
Clinical cut-off: 19JUN2019

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_CRSUpdate_OS/prod/output/oth_fu_26c_19JUN2019_CHON_EFDUR.xls
30MAR2020 16:29

Sonstige Analysen (Datenschnitt: 10.01.2022)

Todesfälle

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Number of patients who died including primary reason

	PERTUZUMAB (N=1811)	PLACEBO (N=1823)	TOTAL (N=3634)
All deaths	140 (7.7%)	175 (9.6%)	315 (8.7%)
Primary reason			
Recurrence of disease	96 (5.3%)	123 (6.7%)	219 (6.0%)
Adverse event	24 (1.3%)	24 (1.3%)	48 (1.3%)
Other	20 (1.1%)	28 (1.5%)	48 (1.3%)

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_dth.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_dth_26d_10JAN2022_CHON.xls
04MAY2022 10:09

Sonstige Analysen (Datenschnitt: 10.01.2022)

DFS Ereignisse mit und ohne Tod

POPULATION: HR negative or node positive ITT
ENDPOINT: DFS (Disease-free survival)
MODEL: --
STUDY: BO25126
DFS events with and without death

	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
All DFS Events		
Total Patients: n (%)	256 (100%)	347 (100%)
Patients with Events		
Contralateral breast cancer	22 (8.6%)	25 (7.2%)
Contralateral or ipsilateral DCIS	7 (2.7%)	16 (4.6%)
Death	25 (9.8%)	28 (8.1%)
Distant recurrence/CNS metastases	132 (51.6%)	174 (50.1%)
Local recurrence	16 (6.3%)	38 (11.0%)
Regional recurrence	11 (4.3%)	14 (4.0%)
Second primary non-breast cancer	43 (16.8%)	52 (15.0%)
All DFS Events without death		
Total Patients: n (%)	231 (100%)	319 (100%)
Patients with Events		
Contralateral breast cancer	22 (9.5%)	25 (7.8%)
Contralateral or ipsilateral DCIS	7 (3.0%)	16 (5.0%)
Distant recurrence/CNS metastases	132 (57.1%)	174 (54.5%)
Local recurrence	16 (6.9%)	38 (11.9%)
Regional recurrence	11 (4.8%)	14 (4.4%)
Second primary non-breast cancer	43 (18.6%)	52 (16.3%)

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_dfsrec.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_dfsrec_26d_10JAN2022_CHON.xls
04MAY2022 10:10

Sonstige Analysen (Datenschnitt: 10.01.2022)

Interventionen (Post Treatment) für Patienten mit DFS-Ereignissen

POPULATION: HR negative or node positive ITT
ENDPOINT: DFS (Disease-free survival)
MODEL: --
STUDY: BO25126
Interventions (post-treatment) for patients with DFS events

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
All DFS Events		
Total Patients: n (%)	256 (100%)	347 (100%)
Pts with Interventions		
>=1	201 (78.5%)	271 (78.1%)
0	55 (21.5%)	76 (21.9%)
1	41 (16.0%)	36 (10.4%)
2	46 (18.0%)	57 (16.4%)
3	30 (11.7%)	61 (17.6%)
4	26 (10.2%)	36 (10.4%)
5	28 (10.9%)	24 (6.9%)
6	8 (3.1%)	13 (3.7%)
7	10 (3.9%)	19 (5.5%)
8	3 (1.2%)	7 (2.0%)
9	2 (0.8%)	3 (0.9%)
10	3 (1.2%)	4 (1.2%)
11	3 (1.2%)	4 (1.2%)
12	0	1 (0.3%)
13	0	2 (0.6%)
14	0	2 (0.6%)
15	0	1 (0.3%)
16	0	1 (0.3%)
31	1 (0.4%)	0

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
Pts with Chemotherapy		
>=1	173 (67.6%)	231 (66.6%)
0	83 (32.4%)	116 (33.4%)
1	48 (18.8%)	40 (11.5%)
2	41 (16.0%)	48 (13.8%)
3	31 (12.1%)	61 (17.6%)
4	20 (7.8%)	26 (7.5%)
5	13 (5.1%)	17 (4.9%)
6	9 (3.5%)	10 (2.9%)
7	6 (2.3%)	13 (3.7%)
8	2 (0.8%)	6 (1.7%)
9	1 (0.4%)	1 (0.3%)
10	1 (0.4%)	2 (0.6%)
11	0	3 (0.9%)
12	0	1 (0.3%)
13	0	1 (0.3%)
14	0	1 (0.3%)
16	0	1 (0.3%)
30	1 (0.4%)	0
Pts with Hormone Therapy		
>=1	2 (0.8%)	7 (2.0%)
0	254 (99.2%)	340 (98.0%)
1	1 (0.4%)	6 (1.7%)
2	1 (0.4%)	0
4	0	1 (0.3%)
Pts with Radiotherapy		
>=1	59 (23.0%)	79 (22.8%)
0	197 (77.0%)	268 (77.2%)
1	42 (16.4%)	56 (16.1%)
2	13 (5.1%)	15 (4.3%)
3	3 (1.2%)	7 (2.0%)
4	1 (0.4%)	0
6	0	1 (0.3%)

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
Pts with Cancer-related Surgery		
>=1	79 (30.9%)	99 (28.5%)
0	177 (69.1%)	248 (71.5%)
1	63 (24.6%)	83 (23.9%)
2	9 (3.5%)	12 (3.5%)
3	4 (1.6%)	1 (0.3%)
4	1 (0.4%)	2 (0.6%)
5	1 (0.4%)	0
6	1 (0.4%)	0
7	0	1 (0.3%)
All DFS Events without death		
Total Patients: n (%)	231 (100%)	319 (100%)
Pts with Interventions		
>=1	201 (87.0%)	271 (85.0%)
0	30 (13.0%)	48 (15.0%)
1	41 (17.7%)	36 (11.3%)
2	46 (19.9%)	57 (17.9%)
3	30 (13.0%)	61 (19.1%)
4	26 (11.3%)	36 (11.3%)
5	28 (12.1%)	24 (7.5%)
6	8 (3.5%)	13 (4.1%)
7	10 (4.3%)	19 (6.0%)
8	3 (1.3%)	7 (2.2%)
9	2 (0.9%)	3 (0.9%)
10	3 (1.3%)	4 (1.3%)
11	3 (1.3%)	4 (1.3%)
12	0	1 (0.3%)
13	0	2 (0.6%)
14	0	2 (0.6%)
15	0	1 (0.3%)
16	0	1 (0.3%)
31	1 (0.4%)	0

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
Pts with Chemotherapy		
>=1	173 (74.9%)	231 (72.4%)
0	58 (25.1%)	88 (27.6%)
1	48 (20.8%)	40 (12.5%)
2	41 (17.7%)	48 (15.0%)
3	31 (13.4%)	61 (19.1%)
4	20 (8.7%)	26 (8.2%)
5	13 (5.6%)	17 (5.3%)
6	9 (3.9%)	10 (3.1%)
7	6 (2.6%)	13 (4.1%)
8	2 (0.9%)	6 (1.9%)
9	1 (0.4%)	1 (0.3%)
10	1 (0.4%)	2 (0.6%)
11	0	3 (0.9%)
12	0	1 (0.3%)
13	0	1 (0.3%)
14	0	1 (0.3%)
16	0	1 (0.3%)
30	1 (0.4%)	0
Pts with Hormone Therapy		
>=1	2 (0.9%)	7 (2.2%)
0	229 (99.1%)	312 (97.8%)
1	1 (0.4%)	6 (1.9%)
2	1 (0.4%)	0
4	0	1 (0.3%)
Pts with Radiotherapy		
>=1	59 (25.5%)	79 (24.8%)
0	172 (74.5%)	240 (75.2%)
1	42 (18.2%)	56 (17.6%)
2	13 (5.6%)	15 (4.7%)
3	3 (1.3%)	7 (2.2%)
4	1 (0.4%)	0
6	0	1 (0.3%)

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
Pts with Cancer-related Surgery		
>=1	79 (34.2%)	99 (31.0%)
0	152 (65.8%)	220 (69.0%)
1	63 (27.3%)	83 (26.0%)
2	9 (3.9%)	12 (3.8%)
3	4 (1.7%)	1 (0.3%)
4	1 (0.4%)	2 (0.6%)
5	1 (0.4%)	0
6	1 (0.4%)	0
7	0	1 (0.3%)
Distant recurrence/CNS metastases		
Total Patients: n (%)	132 (100%)	174 (100%)
Pts with Interventions		
>=1	120 (90.9%)	148 (85.1%)
0	12 (9.1%)	26 (14.9%)
1	22 (16.7%)	13 (7.5%)
2	24 (18.2%)	25 (14.4%)
3	18 (13.6%)	37 (21.3%)
4	19 (14.4%)	22 (12.6%)
5	16 (12.1%)	13 (7.5%)
6	7 (5.3%)	7 (4.0%)
7	7 (5.3%)	12 (6.9%)
8	2 (1.5%)	6 (3.4%)
9	1 (0.8%)	2 (1.1%)
10	1 (0.8%)	4 (2.3%)
11	2 (1.5%)	2 (1.1%)
12	0	1 (0.6%)
13	0	1 (0.6%)
14	0	1 (0.6%)
15	0	1 (0.6%)
16	0	1 (0.6%)
31	1 (0.8%)	0

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
Pts with Chemotherapy		
>=1	109 (82.6%)	140 (80.5%)
0	23 (17.4%)	34 (19.5%)
1	27 (20.5%)	18 (10.3%)
2	23 (17.4%)	28 (16.1%)
3	23 (17.4%)	38 (21.8%)
4	14 (10.6%)	17 (9.8%)
5	8 (6.1%)	9 (5.2%)
6	6 (4.5%)	8 (4.6%)
7	4 (3.0%)	11 (6.3%)
8	2 (1.5%)	4 (2.3%)
9	0	1 (0.6%)
10	1 (0.8%)	2 (1.1%)
12	0	1 (0.6%)
13	0	1 (0.6%)
14	0	1 (0.6%)
16	0	1 (0.6%)
30	1 (0.8%)	0
Pts with Hormone Therapy		
0	132 (100%)	174 (100%)
Pts with Radiotherapy		
>=1	46 (34.8%)	60 (34.5%)
0	86 (65.2%)	114 (65.5%)
1	34 (25.8%)	45 (25.9%)
2	10 (7.6%)	10 (5.7%)
3	2 (1.5%)	4 (2.3%)
6	0	1 (0.6%)
Pts with Cancer-related Surgery		
>=1	33 (25.0%)	26 (14.9%)
0	99 (75.0%)	148 (85.1%)
1	27 (20.5%)	26 (14.9%)
2	4 (3.0%)	0

Analysis Category	PERTUZUMAB (N=1811)	PLACEBO (N=1823)
3	2 (1.5%)	0

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_intv.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_intv_26d_10JAN2022_CHON.xls
28JUN2022 12:59

Sonstige Analysen (Datenschnitt: 10.01.2022)

Zusammenfassung über das erste Auftreten eines DFS-Ereignisses

POPULATION: HR negative or node positive ITT
ENDPOINT: DFS (Disease-free survival)
MODEL: --
STUDY: BO25126
Summary of First Occurrence of an Event

	Pertuzumab + Trastuzumab + Chemotherapy (N=1811)	Placebo + Trastuzumab + Chemotherapy (N=1823)	Patients with more than one event on the same day - Pertuzumab (N=256)	Patients with more than one event on the same day - Placebo (N=347)	Patients with more than one event on the first day: new event later in the study - Pertuzumab (N=30)	Patients with more than one event on the first day: new event later in the study - Placebo (N=48)	Patients with only one event on the same day - Pertuzumab (N=256)	Patients with only one event on the same day - Placebo (N=347)	Patients with only one event on the first day: new event later in the study - Pertuzumab (N=226)	Patients with only one event on the first day: new event later in the study - Placebo (N=299)
Total Patients with DFS Event: n (%)										
DFS event	256 (14.1%)	347 (19.0%)	30 (11.7%)	48 (13.8%)	22 (73.3%)	31 (64.6%)	226 (88.3%)	299 (86.2%)	100 (44.2%)	143 (47.8%)
Category of DFS Event: n (%)										
Locoregional recurrence	27 (1.5%)	52 (2.9%)	3 (1.2%)	2 (0.6%)	2 (6.7%)	1 (2.1%)	24 (9.4%)	50 (14.4%)	10 (4.4%)	24 (8.0%)
Distant recurrence	132 (7.3%)	174 (9.5%)	27 (10.5%)	42 (12.1%)	20 (66.7%)	30 (62.5%)	105 (41.0%)	132 (38.0%)	71 (31.4%)	91 (30.4%)
CNS metastases	42 (2.3%)	40 (2.2%)	4 (1.6%)	2 (0.6%)	4 (13.3%)	1 (2.1%)	38 (14.8%)	38 (11.0%)	27 (11.9%)	27 (9.0%)
Contralateral breast cancer	22 (1.2%)	25 (1.4%)	0	4 (1.2%)	0	0	22 (8.6%)	21 (6.1%)	1 (0.4%)	4 (1.3%)
Second primary non-breast cancer	43 (2.4%)	52 (2.9%)	0	0	0	0	43 (16.8%)	52 (15.0%)	15 (6.6%)	20 (6.7%)
Contralateral or ipsilateral DCIS	7 (0.4%)	16 (0.9%)	0	0	0	0	7 (2.7%)	16 (4.6%)	3 (1.3%)	4 (1.3%)
Death without prior event	25 (1.4%)	28 (1.5%)	0	0	0	0	25 (9.8%)	28 (8.1%)	0	0
Adverse event	12 (0.7%)	9 (0.5%)	0	0	0	0	12 (4.7%)	9 (2.6%)	0	0
Other	13 (0.7%)	19 (1.0%)	0	0	0	0	13 (5.1%)	19 (5.5%)	0	0
Death after prior event: n (%)										
Adverse event	12 (0.7%)	15 (0.8%)	0	0	0	0	12 (4.7%)	15 (4.3%)	12 (5.3%)	15 (5.0%)
Recurrence of disease	93 (5.1%)	123 (6.7%)	20 (7.8%)	27 (7.8%)	20 (66.7%)	27 (56.3%)	73 (28.5%)	96 (27.7%)	73 (32.3%)	96 (32.1%)
Other	7 (0.4%)	9 (0.5%)	0	1 (0.3%)	0	1 (2.1%)	7 (2.7%)	8 (2.3%)	7 (3.1%)	8 (2.7%)

Patients who experience >1 DFS event are reported in the category associated with their earliest DFS event.
If >1 event is reported on the same date, patients are reported in the category according to the following hierarchy: [1] Distant recurrence; [2] Locoregional recurrence; [3] Contralateral breast cancer; [4] Death without prior event.
CNS metastases is a subset of distant recurrence.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_effoex.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_effoex_26d_10JAN2022_CHON_FDFS.xls
11JUL2022 12:36

Sonstige Analysen (Datenschnitt: 10.01.2022)

Unerwünschte Ereignisse die zum Tode führen

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of AEs leading to death

Treatment: PERTUZUMAB (N=1783)

Centre/patient ID	Age/sex/race	Date of first study drug administration	Study day of first Pertuzumab/placebo	Study day of last study drug administration	Day of onset	Day of death	AE preferred term
[redacted]	[redacted]	30JAN2013	64	64	68	68	ROAD TRAFFIC ACCIDENT
[redacted]	[redacted]	20MAR2012	1	59	64	65	FEBRILE NEUTROPENIA
[redacted]	[redacted]	27JUN2013	85	154	173	174	HYPERKALAEMIA
[redacted]	[redacted]	22JAN2013	92	134	154	160	PNEUMONIA ASPIRATION
[redacted]	[redacted]	04FEB2013	93	457	492	760	GASTROINTESTINAL CARCINOMA
[redacted]	[redacted]	02MAY2012	64	421	1846	2652	PANCREATIC CARCINOMA
[redacted]	[redacted]	15NOV2012	1	260	274	275	CEREBRAL HAEMORRHAGE
			1	260	274	275	SUBARACHNOID HAEMORRHAGE
[redacted]	[redacted]	30OCT2012	65	338	297	554	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	01JUN2012	1	344		2834	METASTATIC MALIGNANT MELANOMA
[redacted]	[redacted]	10JUL2013	1	353	1029	1242	METASTATIC MALIGNANT MELANOMA
[redacted]	[redacted]	22NOV2012	1	133	146	175	INTERSTITIAL LUNG DISEASE
[redacted]	[redacted]	17JUN2013	64	337	1107	1261	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	25APR2013	85	121	453	453	CARDIOGENIC SHOCK
[redacted]	[redacted]	02JUL2012	71	135	1334	1334	MITRAL VALVE DISEASE
[redacted]	[redacted]	07NOV2012	99	148	161	175	SEPSIS
[redacted]	[redacted]	13MAR2013	64	148	2333	2336	CARDIAC ARREST
[redacted]	[redacted]	17MAY2012	1	22	1087	1144	GLIOBLASTOMA
[redacted]	[redacted]	26JUN2013	1	365	2530	2813	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	29AUG2012	97	225	288	542	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	14NOV2012	113	260	685	1078	TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED
[redacted]	[redacted]	31AUG2012	88	438	2051	2790	SOFT TISSUE SARCOMA
[redacted]	[redacted]	05FEB2013	86	443	446	738	ACUTE MYELOID LEUKAEMIA

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_aefatal.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_aefatal_26d_10JAN2022_CHNS.xls
20JUN2022 12:07

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: --
MODEL: --
STUDY: BO25126
Listing of AEs leading to death

Treatment: PLACEBO (N=1822)

Centre/patient ID	Age/sex/race	Date of first study drug administration	Study day of first Pertuzumab/placebo	Study day of last study drug administration	Day of onset	Day of death	AE preferred term
[redacted]	[redacted]	25FEB2013	65	421	1052	1231	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	29MAR2013	85	442	1824	2232	PANCREATIC CARCINOMA METASTATIC
[redacted]	[redacted]	20JUN2013		71	80	93	SEPSIS
[redacted]	[redacted]	29OCT2012	89	109	127	129	PNEUMONIA
[redacted]	[redacted]	27NOV2012	85	449	2131	3181	
[redacted]	[redacted]	15APR2013	93	233	184	244	PULMONARY FIBROSIS
[redacted]	[redacted]	12JUN2012	1	1	7	8	INTESTINAL ISCHAEMIA
[redacted]	[redacted]	11SEP2012	1	218	220	582	ADENOCARCINOMA PANCREAS
[redacted]	[redacted]	27FEB2012	72	431	857	983	LUNG NEOPLASM MALIGNANT
[redacted]	[redacted]	13JUL2012	1	358	1440	2070	PANCREATIC CARCINOMA
[redacted]	[redacted]	07JAN2013	64	424	1576	2083	MYELODYSPLASTIC SYNDROME
[redacted]	[redacted]	09JUL2012	92	276	298	851	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	21JUN2012	85	442		1373	CARDIAC FAILURE
[redacted]	[redacted]	01AUG2012		1	9	61	GASTROINTESTINAL PERFORATION
[redacted]	[redacted]	03OCT2012	71	435	1344	1529	MALIGNANT PERITONEAL NEOPLASM
[redacted]	[redacted]	07MAY2013	64	417	2724	2724	CARDIAC ARREST
[redacted]	[redacted]	17DEC2012	100	463	2332	2346	
[redacted]	[redacted]	27DEC2012	84	336	1684	1684	ACUTE MYOCARDIAL INFARCTION
[redacted]	[redacted]	13DEC2012	65	421	2621	2863	MALIGNANT NEOPLASM OF RENAL PELVIS
[redacted]	[redacted]	27JUN2012	86	442	1636	1636	ACUTE MYOCARDIAL INFARCTION
[redacted]	[redacted]	18DEC2012	85	402	403	572	GASTRIC NEOPLASM
[redacted]	[redacted]	11MAY2012		1	18	24	SEPTIC SHOCK
[redacted]	[redacted]	05JUL2013	88	389	370	906	SMALL CELL LUNG CANCER
[redacted]	[redacted]	07MAR2013	1	358	1091	1928	ACUTE MYELOID LEUKAEMIA
[redacted]	[redacted]	20MAR2013	1	1	8	42	COLITIS
[redacted]	[redacted]	29MAR2013	89	447		2203	SARCOMA

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_aefatal.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_aefatal_26d_10JAN2022_CHNS.xls
20JUN2022 12:07

Sonstige Analysen (Datenschnitt: 10.01.2022)

Unerwünschtes Ereignis: Diarrhö

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Diarrhoea
MODEL: --
STUDY: BO25126
Exploration of Diarrhoea Adverse Events by Treatment Regimen

	PERTUZUMAB (N=1783)	PLACEBO (N=1822)
Total patients reporting at least 1 event	1257	824
Number of events per patient		
n	1257	824
Mean (SD)	2.04 (1.96)	1.66 (1.35)
Median	1	1
Min - Max	1.0 - 26.0	1.0 - 18.0
Total number of events	2568 (100%)	1371 (100%)
Resolved	2542 (99.0%)	1354 (98.8%)
Unresolved	26 (1.0%)	17 (1.2%)
NCI CTCAE Grade (all events)		
n	2568 (100%)	1370 (100%)
Grade 1	1706 (66.4%)	983 (71.8%)
Grade 2	676 (26.3%)	312 (22.8%)
Grade 3	183 (7.1%)	75 (5.5%)
Grade 4	3 (0.1%)	0
Period of onset (all events)		
n	2565 (100%)	1368 (100%)
Anthracycline period	261 (10.2%)	265 (19.4%)
Targeted treatment and chemo period	1743 (68.0%)	868 (63.5%)
Targeted treatment post chemotherapy	561 (21.9%)	235 (17.2%)
Targeted treatment cycle at onset^		
n	2046 (100%)	994 (100%)
Cycle 1	753 (36.8%)	381 (38.3%)
Cycle 2	330 (16.1%)	167 (16.8%)
Cycle 3	211 (10.3%)	110 (11.1%)
Cycle 4	151 (7.4%)	65 (6.5%)
Cycle 5	77 (3.8%)	45 (4.5%)
Cycle 6	64 (3.1%)	40 (4.0%)
Cycle 7	57 (2.8%)	24 (2.4%)
Cycle 8	58 (2.8%)	19 (1.9%)
Cycle 9	47 (2.3%)	12 (1.2%)
Cycle 10	43 (2.1%)	16 (1.6%)

	PERTUZUMAB (N=1783)	PLACEBO (N=1822)
Cycle 11	52 (2.5%)	26 (2.6%)
Cycle 12	42 (2.1%)	21 (2.1%)
Cycle 13	39 (1.9%)	15 (1.5%)
Cycle 14	27 (1.3%)	12 (1.2%)
Cycle 15	27 (1.3%)	14 (1.4%)
Cycle 16	33 (1.6%)	11 (1.1%)
Cycle 17	19 (0.9%)	10 (1.0%)
Cycle 18	16 (0.8%)	5 (0.5%)
Cycle 20	0	1 (0.1%)
Time to onset of 1st event (days)		
n	1257	824
Mean (SD)	70.40 (59.18)	72.29 (75.39)
Median	71	66
Min - Max	0.0 - 426.0	1.0 - 474.0
Time from 1st targeted treatment to onset (days)*		
n	1160	700
Mean (SD)	25.43 (48.47)	42.32 (70.33)
Median	8	10
Min - Max	1.0 - 354.0	1.0 - 384.0
Duration of longest event (days)		
n	1242	813
Mean (SD)	96.52 (139.25)	58.39 (111.31)
Median	35	13
Min - Max	1.0 - 811.0	1.0 - 1022.0
Duration of each event (days)		
n	2542	1353
Mean (SD)	52.11 (107.36)	38.11 (90.31)
Median	8	6
Min - Max	1.0 - 811.0	1.0 - 1022.0

Includes all AEs reported from the date of 1st dose of study medication up to 28 days after the last dose of study medication.
Diarrhoea events selected from the PT = 'DIARRHOEA', 'DIARRHOEA INFECTIOUS', 'DIARRHOEA HAEMORRHAGIC', 'DIARRHOEA NEONATAL', or 'POST PROCEDURAL DIARRHOEA'.
^ n = number of events started during the targeted treatment period.
* based on events started during the targeted treatment period.
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ae_diar.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_ae_diar_26d_10JAN2022_CHNS.xls
04MAY2022 10:13

Sonstige Analysen (Datenschnitt: 10.01.2022)

Verteilung der Patienten pro Arm

POPULATION: HR negative or node positive ITT
ENDPOINT: --
MODEL: --
STUDY: BO25126
Disposition of patients per arm

	PERTUZUMAB (N=1811) n (%)	PLACEBO (N=1823) n (%)	TOTAL (N=3634) n (%)
Randomized to study treatment	1811 (100%)	1823 (100%)	3634 (100%)
Received at least one dose of study drug	1794 (99.1%)	1811 (99.3%)	3605 (99.2%)
Completed Pertuzumab/placebo treatment	1533 (84.6%)	1582 (86.8%)	3115 (85.7%)
Discontinued Pertuzumab/placebo treatment	278 (15.4%)	241 (13.2%)	519 (14.3%)
Reason for Pertuzumab/placebo treatment discontinuation			
Adverse event	131 (7.2%)	118 (6.5%)	249 (6.9%)
Death	8 (0.4%)	4 (0.2%)	12 (0.3%)
Pregnancy	1 (<0.1%)	0	1 (<0.1%)
Lost to follow-up	0	1 (<0.1%)	1 (<0.1%)
Non-compliance with study drug	32 (1.8%)	23 (1.3%)	55 (1.5%)
Physician decision	20 (1.1%)	12 (0.7%)	32 (0.9%)
Protocol violation	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Recurrence of disease	20 (1.1%)	28 (1.5%)	48 (1.3%)
Contralateral breast cancer	2 (0.1%)	0	2 (<0.1%)
Withdrawal by subject	38 (2.1%)	35 (1.9%)	73 (2.0%)
Other	25 (1.4%)	17 (0.9%)	42 (1.2%)
Entered follow-up period	1788 (98.7%)	1805 (99.0%)	3593 (98.9%)
Completed follow-up period	0	0	0
Discontinued follow-up period	493 (27.2%)	561 (30.8%)	1054 (29.0%)
Reason for discontinuation of follow-up period			
Adverse event	22 (1.2%)	26 (1.4%)	48 (1.3%)
Death	23 (1.3%)	29 (1.6%)	52 (1.4%)
Lost to follow-up	57 (3.1%)	57 (3.1%)	114 (3.1%)
Physician decision	9 (0.5%)	12 (0.7%)	21 (0.6%)
Recurrence of disease	158 (8.7%)	232 (12.7%)	390 (10.7%)
Contralateral breast cancer	22 (1.2%)	21 (1.2%)	43 (1.2%)
Withdrawal by subject	180 (9.9%)	165 (9.1%)	345 (9.5%)
Other	22 (1.2%)	19 (1.0%)	41 (1.1%)

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ds.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_ds_26d_10JAN2022_CHON.xls
04MAY2022 10:06

POPULATION: Intent-to-Treat Population
ENDPOINT: --
MODEL: --
STUDY: BO25126
Disposition of patients per arm

	PERTUZUMAB (N=2400) n (%)	PLACEBO (N=2404) n (%)	TOTAL (N=4804) n (%)
Randomized to study treatment	2400 (100%)	2404 (100%)	4804 (100%)
Received at least one dose of study drug	2378 (99.1%)	2391 (99.5%)	4769 (99.3%)
Completed Pertuzumab/placebo treatment	2028 (84.5%)	2100 (87.4%)	4128 (85.9%)
Discontinued Pertuzumab/placebo treatment	372 (15.5%)	304 (12.6%)	676 (14.1%)
Reason for Pertuzumab/placebo treatment discontinuation			
Adverse event	177 (7.4%)	149 (6.2%)	326 (6.8%)
Death	9 (0.4%)	6 (0.2%)	15 (0.3%)
Pregnancy	1 (<0.1%)	0	1 (<0.1%)
Lost to follow-up	0	1 (<0.1%)	1 (<0.1%)
Non-compliance with study drug	43 (1.8%)	29 (1.2%)	72 (1.5%)
Physician decision	30 (1.3%)	15 (0.6%)	45 (0.9%)
Protocol violation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Recurrence of disease	20 (0.8%)	29 (1.2%)	49 (1.0%)
Contralateral breast cancer	2 (<0.1%)	0	2 (<0.1%)
Withdrawal by subject	55 (2.3%)	47 (2.0%)	102 (2.1%)
Other	34 (1.4%)	25 (1.0%)	59 (1.2%)
Entered follow-up period	2369 (98.7%)	2381 (99.0%)	4750 (98.9%)
Completed follow-up period	0	0	0
Discontinued follow-up period	654 (27.3%)	693 (28.8%)	1347 (28.0%)
Reason for discontinuation of follow-up period			
Adverse event	32 (1.3%)	36 (1.5%)	68 (1.4%)
Death	31 (1.3%)	35 (1.5%)	66 (1.4%)
Lost to follow-up	79 (3.3%)	75 (3.1%)	154 (3.2%)
Physician decision	17 (0.7%)	16 (0.7%)	33 (0.7%)
Recurrence of disease	177 (7.4%)	258 (10.7%)	435 (9.1%)
Contralateral breast cancer	28 (1.2%)	22 (0.9%)	50 (1.0%)
Withdrawal by subject	260 (10.8%)	225 (9.4%)	485 (10.1%)
Other	30 (1.3%)	26 (1.1%)	56 (1.2%)

Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_ds.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_ds_26d_10JAN2022_IT.xls
04MAY2022 10:07

Sonstige Analysen (Datenschnitt: 10.01.2022)

Follow-up time (UE, SUE, OS, DFS)

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Median follow-up duration (safety 1)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1783)	PLACEBO (N=1822)	TOTAL (N=3605)
n	1783	1822	3605
Median	14,92	14,95	14,95
Min - Max	0.1 - 18.5	0.0 - 112.8	0.0 - 112.8

Follow-up time is calculated as median[(min(data cut date, death date, last date alive, last dose of study treatment + 28 days, initiation of subsequent anti-cancer therapy)- randomization date + 1) / 30.4375].
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_fu_26d_10JAN2022_CHNS_SAF1DUR.xls
04MAY2022 10:11

POPULATION: HR negative or node positive safety evaluable
ENDPOINT: Median follow-up duration (safety 2)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1783)	PLACEBO (N=1822)	TOTAL (N=3605)
n	1783	1822	3605
Median	99,88	99,65	99,78
Min - Max	0.1 - 120.1	0.0 - 117.3	0.0 - 120.1

Follow-up time is calculated as median[(min(data cut date, death date, last date alive,
initiation of subsequent anti-cancer therapy)- randomization date + 1) / 30.4375].
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_fu_26d_10JAN2022_CHNS_SAF2DUR.xls
04MAY2022 10:12

POPULATION: HR negative or node positive ITT
ENDPOINT: Median follow-up duration (efficacy)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1811)	PLACEBO (N=1823)	TOTAL (N=3634)
n	1811	1823	3634
Median	99,71	99,81	99,78
Min - Max	0.0 - 120.1	0.0 - 117.3	0.0 - 120.1

Follow-up time is calculated as median[(min(data cut date, death date, last date alive)- randomization date + 1) / 30.4375].
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_fu_26d_10JAN2022_CHON_EFDUR.xls
04MAY2022 10:11

POPULATION: HR negative or node positive ITT
ENDPOINT: Median follow-up duration (efficacy 2)
MODEL: --
STUDY: BO25126
Median follow-up (months) by endpoint and arm

	PERTUZUMAB (N=1811)	PLACEBO (N=1823)	TOTAL (N=3634)
n	1811	1823	3634
Median	99,35	99,06	99,15
Min - Max	0.0 - 120.1	0.0 - 117.3	0.0 - 120.1

Follow-up time is calculated as median[(min(data cut date, death date, last date alive, date of the first occurrence of an invasive disease-free survival event including second primary non-breast cancer event or contralateral or ipsilateral DCIS)-randomization date + 1) / 30.4375].
Clinical cut-off: 10JAN2022

Program: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_base/prod/program/oth_fu.sas
Output: root/clinical_studies/RO4368451/CDPT3497/BO25126/data_analysis/ACE_OSIA3/prod/output/oth_fu_26d_10JAN2022_CHON_EF2DUR.xls
04MAY2022 10:11